RECORD NO. 24-5294
[ORAL ARGUMENT HAS NOT BEEN SCHEDULED]

In The

United States Court Of Appeals

For The D.C. Circuit

PUBLIC EMPLOYEES FOR ENVIRONMENTAL RESPONSIBILITY; CENTER FOR ENVIRONMENTAL HEALTH,

Plaintiffs - Appellants,

v.

LEE M. ZELDIN, AS ADMINISTRATOR OF THE UNITED STATES ENVIRONMENTAL PROTECTION AGENCY; ENVIRONMENTAL PROTECTION AGENCY,

Defendants - Appellees,

INHANCE TECHNOLOGIES LLC,

Intervenor for Appellee.

ON APPEAL FROM THE UNITED STATES DISTRICT COURT FOR THE DISTRICT OF COLUMBIA

OPENING BRIEF OF PLAINTIFF-APPELLANTS PUBLIC EMPLOYEES FOR ENVIRONMENTAL RESPONSIBILITY AND CENTER FOR ENVIRONMENTAL HEALTH

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CERTIFICATE AS TO PARTIES, RULINGS, AND RELATED CASES

Plaintiffs-Appellants submit thus Certificate of Parties, Rulings and Related Cases under Circuit Rule 28(a)(1).

A. Parties

Plaintiffs-Appellants

Public Employees for Environmental Responsibility

Center for Environmental Health

Defendants-Appellees

U.S. Environmental Protection Agency

Lee Zeldin, in his capacity as Administrator of the U.S. Environmental Protection Agency

Intervenor-Appellee

Inhance Technologies LLC

B. Rulings Under Review

The decision at issue on appeal is the District Court's Order of December 11, 2024 dismissing plaintiffs' Complaint. JA 193 Judge Boasberg's memorandum opinion of the same date provided the basis for the order. JA 194.

C. Related Cases

None.

/s/ Robert M. Sussman
Robert M. Sussman

Counsel for Plaintiffs-Appellants

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GLOSSARY

CEH	Center for Environmental Health
EPA	Environmental Protection Agency
Inhance	Inhance Technologies LLC
PFAS	Per- and poly-fluoroalkyl substances
PFOA	Perfluorooctanoic acid
PEER	Public Employees for Environmental Responsibility
SNUR	Significant New Use Rule
TSCA	Toxic Substances Control Act

INTRODUCTION

This citizens' suit case involves the failure of EPA to carry out mandatory duties under Section 4(f) of the Toxic Substances Control Act ("TSCA"), 15 U.S.C. § 2601, the nation's principal law for managing risks from chemicals. Section 4(f), 15 U.S.C. § 2603(f), is an action-forcing provision that directs EPA to take expedited measures to protect the public from chemicals that present unusually urgent and dangerous risks to health. Here, the chemical presenting these risks is perfluorooctanoic acid ("PFOA"), a known carcinogen and the most harmful of the class of per- and poly-fluoroalkyl substances ("PFAS"). These substances, often called "forever chemicals," are persistent, accumulate in the environment and human blood, and have raised widespread and urgent health and environmental concerns in the U.S. and around the world.

As EPA and scientific experts have recognized, PFOA and other PFAS are formed during the fluorination of plastic containers, a chemical treatment applied to these containers by Intervenor-Appellee Inhance Technologies LLC ("Inhance"). According to EPA, these PFAS leach into the container contents and subject users and bystanders to risks of cancer and other serious harms even at minuscule levels of exposure. Inhance fluorinates approximately 200 million containers each year, which are distributed throughout the economy and used, handled and disposed of by several million consumers, workers and members of the public.

The facts alleged in Plaintiff-Appellants' Complaint establish that, no later than March 29, 2023, the Agency had a "reasonable basis to conclude" that the formation of PFOA during fluorination "presents a significant risk of serious or widespread harm to human beings," starting the 180-day clock for expedited EPA action under Section 4(f). As of that date if not earlier, EPA was in possession of information demonstrating that (i) the Inhance fluorination process consistently formed PFOA and several other PFAS in plastic containers and their contents to which millions of people were exposed and (ii) PFOA is a known human carcinogen with no safe level of exposure. Within 180 days, EPA thus had a non-discretionary duty to "initiate applicable action" under sections 5, 6 or 7 to "prevent or reduce [the risk] to a sufficient extent."

In late 2023, based on a comprehensive risk assessment, EPA issued an order under Section 5(f) of TSCA, 15 U.S.C. § 2604(f), prohibiting Inhance from forming PFOA and two other PFAS during fluorination. JA 128-179. The Fifth Circuit vacated this order in March 2024, holding that EPA exceeded its authority under TSCA Section 5. *Inhance Technologies, LLC v. USEPA,* 96 F.4th 888 (5th Cir. 2024). However, because the court's decision did not question the order's determination of unreasonable risk and extensive scientific findings, EPA's Section 4(f) statutory obligations remained outstanding. Thus, under the express wording of TSCA, it was still required to take action to prevent or reduce

fluorination risks under TSCA Sections 6 or 7. Nonetheless, EPA has neither acknowledged that Section 4(f) applies to fluorinated containers nor taken any action under Sections 6 or 7 satisfying its non-discretionary duties to "prevent or reduce [the risk] to a sufficient extent."

On July 25, 2024, Plaintiff-Appellants filed a citizens' suit under TSCA Section 20(a)(2), 15 U.S.C. § 2619(a)(2), to compel EPA to comply with Section 4(f). However, on December 11, 2024, District Judge Boasberg dismissed Plaintiff-Appellants' Complaint as moot, finding that limited actions taken by EPA in mid-2024 under Section 21 of TSCA, 15 U.S.C. § 2620, satisfied its statutory obligations. JA193-205.

This determination was incorrect. The actions cited by the District Court were (i) a cursory and non-committal letter to Plaintiff-Appellants and other groups purporting to "grant" their petition under TSCA Section 21 for rulemaking on fluorinated containers and (ii) a short Federal Register notice seeking limited information that might be relevant to future regulation. JA38-46. Nowhere did the letter and notice initiate rulemaking or other actions that would "prevent or reduce" the health threats of these containers "to a sufficient extent." Thus, the District Court's conclusion that EPA had complied with Section 4(f) and the case was moot was contrary to its plain language and purpose of promptly protecting against high-concern chemicals that threaten public health.

The District Court also dismissed Plaintiffs-Appellants' separate claim that Section 7 of TSCA, 15 U.S.C. § 2606, imposes an enforceable duty on EPA to bring an "imminent hazard" case against Inhance in the district courts. However, both the text of Section 7(a)(2) and TSCA's legislative history confirm that EPA has a non-discretionary duty to file such a suit if: (i) the chemical at issue meets the definition of "imminently hazardous chemical substance" in Section 7(f); and (ii) EPA has not issued an "immediately effective" Section 6(a) rule addressing its risks. Based on the allegations in Plaintiff-Appellants' Complaint, both of these conditions have been met. Accordingly, the District Court's determination that the Complaint fails to allege violation of a non-discretionary duty under Section 7 must be vacated.

EPA's interest in the urgent health threat it recognized over two years ago has now waned and its limited actions have been half-hearted and pro forma. Without the prod of judicial relief, years will likely pass before EPA takes more meaningful measures to address fluorination and it could well do nothing at all. The mandatory duties Congress created under TSCA were designed to avoid such open-ended and indefinite delays in protecting against serious and immediate risks. But with EPA showing no inclination to move forward, only enforcement of its non-discretionary duties by the District Court will spur the Agency to do what TSCA demands.

STATEMENT OF JURISDICTION

This Court has jurisdiction under Section 20 of the Toxic Substances Control Act. 15 U.S.C. § 2619 and 28 U.S.C. § 1331. The final order was filed December 11, 2024, and a timely notice of appeal having been filed on December 26, 2024, this Court has jurisdiction under 28 U.S.C. § 1291.

STATEMENT OF ISSUES

1. Do Plaintiff-Appellants Public Employees for Environmental Responsibility ("PEER") and Center for Environmental Health ("CEH") have associational standing based on the substantial exposure to PFOA by two of their senior employees and PFOA's known serious cancer risks?
2. Since Defendant-Respondent EPA did not take action to prevent or reduce the risk of fluorinated containers as required by Section 4(f) of TSCA, was it error for the District Court to dismiss the Complaint as moot because EPA had afforded all the relief that Section 4(f) of TSCA obligated it to provide?
3. Was EPA under a non-discretionary duty to take action within 180 days after receiving information triggering Section 4(f) of TSCA?
4. Was this duty enforceable under the citizens' suit authority in TSCA section 20?
5. Was section 4(f) triggered on or before March 29, 2023, by which EPA was fully aware of the presence of PFOA in millions of fluorinated plastic containers and had determined that PFOA causes cancer in people at any level of exposure?

6. Did EPA have an enforceable duty under Section 7 of TSCA to file an imminent hazard action against Inhance given EPA's failure to issue an "immediately effective" rule under Section 6(d) protecting against the imminent risks to health presented by PFOA formation during fluorination?

PERTINENT STATUTES AND REGULATIONS

Pertinent statutes and regulations are provided in the addendum accompanying this Brief.

STATEMENT OF THE CASE

A. Overview of TSCA

"Congress enacted TSCA in 1976 with the express purpose of limiting the public health and environmental risks associated with exposure to . . . toxic chemical substances." *Physicians Comm. For Responsible Med. v. Johnson*, 436 F.3d 326, 327 (2d Cir. 2006). Disappointed in EPA's slow progress in implementing the law, Congress overhauled and strengthened TSCA in 2016 with overwhelming bi-partisan support. These amendments enhance the core chemical regulatory authorities in TSCA by accelerating the pace of EPA risk evaluations and risk management rules and strengthening health and environmental protections against unsafe chemicals. To that end, the amended law contains several action-forcing directives and deadlines for carrying them out.

The provisions of amended TSCA relevant to this case are as follows:

- **Section 5,** 15 U.S.C. § 2604, authorizes the review and regulation of new chemical substances and significant new uses of existing chemicals before they enter commercial production. Under the 2016 amendments, EPA must make an affirmative determination of safety under Section 5(a)(3) for these chemicals and uses before they may enter commerce. If EPA finds that a new chemical or significant new use presents an unreasonable risk of injury, it *"shall"* issue an order under Section 5(f) banning or restricting production to the extent necessary to protect against the unreasonable risk (emphasis added).
- **Section 6,** 15 U.S.C. § 2605, requires EPA to conduct rulemaking on existing chemicals determined to present unreasonable risks of injury to health or the environment. Section 6(a) provides that, for any chemical that EPA determines "presents an unreasonable risk," the Administrator *shall* by rule" impose one of more of the restrictions authorized in Sections 6(a)(1)-(7). 15 U.S.C. § 2605(a)(1)-(7) (emphasis added), including prohibitions or limitations on manufacture, processing, use, distribution and/or disposal. Section 6(c)(1) further directs that EPA "*shall propose*" a Section 6(a) rule within one year of completing its evaluation of unreasonable risks and "*shall publish* . . . a final rule not

later than 2 years after" finalizing that risk evaluation (emphasis added).

- **Section 7(a)(2),** 15 U.S.C. § 2606(a)(2), provides that, if EPA has not promulgated an immediately effective rule under Section 6(d)(3), it "*shall*" commence a suit for immediate injunctive relief where a substance or mixture is "imminently hazardous" (emphasis added). Under Section 7(f), the term "imminently hazardous" refers to a chemical which "presents an imminent and unreasonable risk of serious or widespread injury to health or the environment."
- **Section 4(f),** 15 U.S.C. § 2603(f), compels EPA to act promptly to address urgent risks of harm to health from unusually dangerous chemicals.[1] Such action is triggered when information available to EPA "indicates to [the Agency] that there may be a reasonable basis to conclude that a chemical substance or mixture presents a significant risk of serious or widespread harm to human beings." Upon acquiring such information, EPA "*shall* . . . initiate applicable action under section [5, 6 or 7] to prevent or reduce such risk to a sufficient extent" or determine that the risk is "not unreasonable" (emphasis added). Such action must be

[1] Under the original law, Section 4(f) only applied to "cancer, gene mutations and birth defects." The 2016 amendments expanded its scope to all "harm to human beings."

taken "within the 180-day period beginning on the date of the receipt of the information" but can be extended by 90 days for "good cause."

- **Section 20(a)(2)**, 15 U.S.C. § 2619(a)(2), authorizes citizens' civil actions in the district courts to compel the Administrator "to perform any act or duty under this Act which is not discretionary."
- **Section 21,** 15 U.S.C. § 2620, authorizes citizens to petition EPA to issue rules or orders under Sections 4, 5, 6 and 8 of TSCA. EPA must respond to these petitions within 90 days. If it "grants" the petition, the Agency must "promptly commence an appropriate proceeding." The law does not prescribe a timetable for this proceeding.

B. Formation of PFAS During Fluorination

Inhance's business is treating high-density polyethylene and other plastic containers by post-mold "fluorination," a process in which fluorine gas is applied to the molded container under high temperatures to improve its barrier properties (i.e., its impermeability**).** Complaint ¶52, JA 18. After molding the plastic resin into a fixed size and shape, container manufacturers ship them to Inhance facilities to be fluorinated. Id. The fluorinated containers are then sent to distributors or product suppliers who add the container contents and ship the filled containers to downstream users. Inhance fluorinates approximately 200 million containers per year. *Id*. ¶53. JA18.

Containers fluorinated by Inhance are widely used for a variety of consumer, commercial and industrial products. Examples include household spray cleaners, countertop polish, floor cleaners and polish, furniture wipes, spray pesticides and herbicides, hose-end sprayer herbicides, commercial pesticides, cosmetics, food packaging and industrial chemical storage. *Id.* ¶54, JA 18. Inhance also fluorinates fuel tanks for handheld and ground-supported outdoor power equipment (e.g., mowers, string trimmers), power sports (e.g., all-terrain vehicles, personal watercraft, 4x4s), vessels (e.g., motorized boats), and portable fuel storage containers (e.g., gas cans). *Id*. ¶55, JA 19; Declaration of Kyla Bennett ¶¶18-21, JA186-189.

In the fall of 2020, Plaintiff-Appellant PEER and the Massachusetts Department of Environmental Protection tested fluorinated containers of Anvil 10+10®, a pesticide used for mosquito control, and detected the presence of multiple PFAS, including PFOA. Complaint ¶¶ 58-61, JA12; Bennett Declaration ¶¶4-5, JA180-81. In December 2020, EPA itself tested unused fluorinated containers obtained from the distributor of Anvil 10+10® and detected these PFAS in the rinsates (solvents used to extract chemical compounds). *Id.* On January 14, 2021, EPA issued a press release "making new information available about EPA testing that shows PFAS contamination from fluorinated containers." *Id*.

In early 2021, EPA issued the first of two subpoenas to Inhance to investigate whether it was in violation of EPA's 2020 Significant New Use Rule ("SNUR") under TSCA Section 5(a)(2), 15 U.S.C. 2604(a)(2), for certain long-chain PFAS. *Id*. ¶71, JA22. Over the ensuing months, EPA conducted two additional rounds of testing confirming formation of 13 different PFAS in fluorinated containers. *Id.* ¶¶ 62-63, JA20. Similar results were reported by several academic researchers and independent testing laboratories. Id. ¶64, JA20-21. In the aggregate, this growing body of data demonstrated that PFOA and several other PFAS were consistently found in the walls of fluorinated containers and readily leached into the container contents and that, over time, the concentrations of PFAS in the containers and their contents increased. Id. ¶102-103, JA29; Bennett Declaration ¶5, JA180-81. Inhance itself has admitted to EPA that the production of PFAS is "an apparently unavoidable aspect of fluorination of HDPE containers" and "there is no easy solution to the problem." Complaint ¶56, JA19.

C. The Threat of PFOA and Other PFAS to Public Health

EPA has recognized that "harmful [PFAS] are an urgent public health and environmental issue facing communities across the United States."[2] As EPA has explained, "[d]ue to their strong carbon-fluorine bonds, many PFAS can be very

[2] https://www.epa.gov/system/files/documents/2021-10/pfas-roadmap_final-508.pdf.

persistent in the environment with degradation periods of years, decades, or longer under natural conditions."[3] Often called "forever chemicals," PFAS "remain chemically and thermally stable , ... making them resistant to hydrolysis, photolysis, microbial degradation, and metabolism. These properties are what make . . . . some PFAS extremely persistent in the human body and the environment." *EPA*, *PFAS National Primary Drinking Water Regulation Rulemaking,* 88 Fed. Reg. 18638, 18643 (March 29, 2023) (citations omitted). PFAS have been detected in the blood of the general U.S. population, with 98 percent of those sampled showing detectable levels of these compounds. 88 Fed. Reg. at 18643. PFAS are associated with "significant and diverse" adverse health effects that "include (but are not limited to): cancer and effects on the liver (*e.g.,* liver cell death), growth and development (*e.g.,* low birth weight), hormone levels, kidney, immune system, lipid levels (*e.g.,* high cholesterol), the nervous system, and reproduction." *Id.*

PFOA, which is consistently formed during fluorination, is the most dangerous PFAS for which health effects data are available. In 1999, responding to concerns about its persistence and accumulation in human blood and wildlife, 3M Corporation, the largest manufacturer of PFOA, announced a halt on its

[3] https://www.epa.gov/sites/default/files/2019-02/documents/pfas_action_plan_021319_508compliant_1.pdf.

manufacture and use. Complaint ¶83, JA25. Shortly thereafter, PFOA was implicated in large-scale contamination of drinking water near a DuPont facility in West Virginia. Follow-up studies funded by the company as part of a legal settlement demonstrated links to cancer and a host of other health problems in the exposed population. *Id.* ¶84, JA25.

On September 27, 2002, the then-Director of the EPA Office of Pollution Prevention and Toxics wrote that "[t]he reproductive/developmental toxicity data, the carcinogenicity data, and the blood monitoring data reviewed in the interim revised hazard assessment raise the possibility that PFOA might meet the criteria for action under section 4(f) of" TSCA. Id. ¶¶85-86, JA18-19. EPA reiterated that Section 4(f) could apply to PFOA in a 2003 Federal Register notice. 68 Fed. Reg. 18626 (April 16, 2003).

In 2006, under pressure from EPA, the principal manufacturers of PFOA and similar long-chain PFAS formed a PFOA Stewardship Program with a goal of reducing and then eliminating their manufacture, use and environmental release by 2015. 80 Fed. Reg. 2885, 2888 (January 21, 2015). The producers fulfilled these commitments, ceasing production of PFOA by the end of 2015. EPA then sought to formalize this phase out by proposing a SNUR under section 5(a)(2) of TSCA in January 2015 because of concern that uses of PFOA and other long-chain PFAS "could be reinitiated in the future," which "could increase the magnitude and

duration of exposure to humans and the environment." 80 Fed. Reg. at 2890. The Agency issued a final SNUR on July 27, 2020 (85 Fed. Reg. 45109), which described at length the persistence and bioaccumulation of PFOA and its numerous health effects. 85 Fed. Reg. at 45113.

Although EPA had been concerned by the harmful effects of PFOA since the early 2000s, the Biden Administration reevaluated the PFOA data-base in anticipation of regulating its levels in drinking water. Based on EPA's new health assessment, PFOA was selected as one of six PFAS for which the Agency developed National Primary Drinking Water Regulations under the Safe Drinking Water Act. The proposed regulations, published on March 29, 2023, 88 Fed. Reg. 18639, stated: "Following a systematic review of available human epidemiological and animal toxicity studies, EPA has determined that PFOA … [is] likely to cause cancer (*e.g.,* kidney and liver cancer) and that there is no dose below which … [it] is considered safe." EPA accordingly proposed to set the health-based value (the Maximum Contaminant Level Goal), at zero. *Id.* EPA's final drinking water regulations, promulgated on April 26, 2024, reiterated that PFOA is "*Likely to be Carcinogenic to Humans* based on sufficient evidence of carcinogenicity in humans and animals" and "that there is no known threshold for carcinogenicity." 89 Fed. Reg. at 32564 (emphasis in original). The final regulations finalized a Maximum Contaminant Level Goal of zero, emphasizing that there was no level of

exposure at which "known or anticipated adverse effects on the health of persons" do not occur. *Id.*

D. EPA and Inhance Actions under the SNUR Addressing PFAS Formation During Fluorination

Section 5(a)(1)(B) of TSCA, 15 U.S.C. § 2604(a)(1)(B), directs parties subject to a SNUR to submit Significant New Use Notices to EPA at least 90 days before the anticipated commencement of manufacture. Manufacture may not proceed until EPA has conducted a review of the notices, made a risk determination for the proposed new use, and issued an order under Section 5(e) or 5(f) restricting the use if warranted by the risk.

Because Inhance had not previously submitted these notices yet was continuing to produce long-chain PFAS, EPA issued a Notice of Violation on March 1, 2022 determining that its PFAS formation during fluorination was a violation of the SNUR. Complaint ¶¶68-69, JA22.[4] The Notice demanded that Inhance remedy the claimed violation by ceasing PFAS production, but it refused and continued forming PFAS during its fluorination process *Id*. ¶70, JA22.

[4] EPA brought an enforcement action against Inhance in the Eastern District of Pennsylvania on December 19, 2022. *United States v. Inhance Techs. LLC,* No. 22-5055 (E.D. Pa.). Plaintiff-Intervenors intervened in the case and moved for summary judgment and an injunction. EPA filed but then withdrew a limited summary judgment motion on liability. Ultimately, the Agency filed a notice of voluntary dismissal two years after the case was brought and Plaintiff-Intervenors followed suit.

However, on December 30, 2022, without ceasing fluorination, Inhance belatedly filed the required notices for the manufacture of PFOA and eight other PFAS during the fluorination process. *Id*. ¶70; 88 Fed. Reg. 10320 (February 17, 2023). The notices contained voluminous information and data on fluorination and the distribution and use of fluorinated containers. Complaint ¶71 JA 22.

EPA's review of the Significant New Use Notices culminated in issuance of a December 1, 2023 order to Inhance under TSCA Section 5(f) that was supported by a comprehensive risk assessment. *Id.* ¶73-74, JA22-23; JA128-179. The Section 5(f) order applied to PFOA and two other long-chain PFAS known to cause harmful health effects. It determined under TSCA Section 5(a)(3)(A) that "manufacture, processing, distribution in commerce, use, and disposal [of these PFAS] . . . presents an unreasonable risk of injury to health or the environment."[5] *Id*. ¶¶103-106, JA30; JA132-36. Based on this determination, the order prohibited production of the three PFAS during fluorination and banned the processing, distribution in commerce, use and disposal of fluorinated containers in which these PFAS were present. JA135-137.

[5] Because its Section 5(f) order determined that PFOA formation during fluorination presents an unreasonable risk, EPA could not now find that these risks are "not unreasonable" under Section 4(f), a finding that would eliminate the need to initiate "applicable action" under sections 5, 6 or 7.

E. Invalidation of the EPA 5(f) Order by the Fifth Circuit

The EPA order would have become effective on February 28, 2024 but was stayed by the Fifth Circuit Court of Appeals on December 12, 2023 and vacated in its March 2, 2024 decision. *Inhance Technologies, LLC v. USEPA,* 96 F.4th 888 (5th Cir. 2024). The Court held that because *Inhance* was fluorinating containers before proposal of the SNUR in 2015, its fluorination process could not be designated as a "significant new use" under TSCA Section 5 and the order was invalid. 96 F.4th at 892-95. However, the Fifth Circuit declined to reach the merits of Inhance's challenges to the scientific and evidentiary basis for the order and thus did not cast any doubt on the validity of EPA's unreasonable risk determination. The court also "hasten[ed] to add" that EPA could "properly proceed" to regulate the fluorination process under Section 6 of TSCA. *Id*. at 895.

F. Section 21 Petition for Rulemaking on Fluorination

Concerned that the Fifth Circuit decision blocked action to abate the serious health threat of fluorinated containers, Plaintiff-Appellants and five other groups filed a petition under Section 21 of TSCA on April 11, 2024 seeking rulemaking under section 6. JA47-180. The petition emphasized that EPA's Section 5(f) order and supporting risk assessment had already determined that PFOA and two other PFAS presented an unreasonable risk to health and only a prohibition on PFAS formation during fluorination could prevent harmful exposure to the three PFAS.

JA50-54. The petition asked EPA to promptly propose a rule under Section 6(a) imposing such a prohibition and make that rule immediately effective under Section 6(d)(3)(A), 15 U.S.C. § 2605(d)(3)(A). JA62-63.

EPA responded to the petition in a brief letter dated July 20, 2024. JA38-41. While purporting to "grant" the petition, the letter made no commitment to propose a Section 6(a) rule or set a schedule for further action. Instead, without citing its previous determination of unreasonable risk under Section 5(f), EPA noted that PFAS in fluorinated containers presented a "risk of concern" and merely committed to "promptly commence an appropriate proceeding under TSCA Section 6." JA40. The letter provided no details on the schedule or goals of that "proceeding" beyond its intent "to request information."

EPA followed up on September 30, 2024 with a terse Federal Register notice requesting information on three questions relating to fluorinated containers. 89 Fed. Reg. 79581. JA42-46. Beyond this limited information request, the notice likewise did not address the timing or substance of any actions EPA might take to address the health risks of fluorinated containers.

Worried that EPA's response to their Section 21 petition would be inadequate, on May 17, 2024, PEER and CEH sent a notice of intent to sue EPA under Section 20(b)(2) to compel it to comply with its obligations under Section 4(f). Complaint ¶¶ 47-51, JA17-18. When EPA's lackluster petition response and

failure to acknowledge their notice letter confirmed their fears, Plaintiff-Appellants filed suit against EPA on July 25, 2024.

SUMMARY OF ARGUMENT

1. Plaintiff-Appellants PEER and CEH meet the requirements for associational standing in *Hunt v. Wash. State Apple Adver. Comm'n*, 432 U.S. 333, 343 (1977), because the interests they seek to protect are germane to the organizations' purposes, neither the claim asserted nor the relief requested requires the participation of individual members in the lawsuit, and their supporters and staff would have standing to sue in their own right. Under *Hunt* and subsequent cases, associational standing can apply to non-membership organizations if their supporters or staff possess the "indicia of membership," such as supporting and influencing the work of the organization. Two senior employees – Dr. Kyla Bennett of PEER and Thomas Fox of CEH -- have submitted declarations (included in an addendum to this Brief) demonstrating that they (i) hold important positions of influence over the work of their organizations, (ii) have experienced ongoing and substantial exposure to PFOA from fluorinated containers and (iii) their health has been endangered by this exposure. The harm they have experienced and will continue to suffer is directly "traceable" to EPA's failure to prohibit PFAS formation during fluorination and would be "redressed" if the District Court ordered the Agency

perform its obligations under Section 4(f). This Court should thus uphold PEER and CEH's standing to sue.

2. While acknowledging that Plaintiff-Appellants had asserted valid claims under Sections 4 and 20 of TSCA, the lower court dismissed these claims as moot on the ground that Plaintiff-Appellants had received the only remedy to which they were entitled under Section 4(f). JA195. Had the court applied the correct interpretation of TSCA, it would have concluded that EPA has in fact failed to remedy its violations of Section 4(f) and there is an ongoing "case or controversy" that precludes mootness.

3. Section 20(a)(2) of TSCA, 15 U.S.C. § 2619(a)(2), provides that "any person may commence a civil action . . . against the Administrator to perform any act or duty under this Act which is not discretionary." Under Section 4(f), EPA "*shall* . . . initiate applicable action under section [5, 6 or 7]" when it obtains information "that there may be a reasonable basis to conclude that a chemical substance . . . presents a significant risk of serious or widespread harm" (emphasis added). EPA must take this action within 180 days of the "receipt of such information." The use of "shall," coupled with an explicit deadline for EPA action, creates a "non-discretionary duty" under Section 4(f) enforceable in a citizens' suit under Section 20(a)(2).

4. By the end of 2022, EPA knew that Inhance fluorinated 200 million containers a year; that PFOA and several other PFAS were consistently present in these containers and their contents; that the containers were used in numerous sectors of the economy, exposing millions of consumers and workers to PFAS; and that these PFAS were released into the environment during the fluorination process, downstream use, and disposal. As of March 29, 2023, EPA had also determined in its proposed PFAS drinking water rule that PFOA is "likely to cause cancer (*e.g.,* kidney and liver cancer) and there is no dose below which … [it] is considered safe." In short, by March 29, 2023 if not earlier, EPA had a "reasonable basis" to conclude that PFOA formation during fluorination met the threshold for "initiat[ing] applicable action" under Section 4(f). Thus, EPA had a non-discretionary duty to take this action *no later than September 25, 2023 but failed to do so.*

5. Nonetheless, the District Court erroneously found that EPA discharged that duty in 2024 by: (i) a brief letter "granting" Plaintiff-Appellants' TSCA Section 21 petition for Section 6(a) rulemaking and (ii) a short Federal Register notice requesting information that EPA deemed relevant to that rulemaking. JA195-97, 199-202. This conclusion was contrary to the plain language and intent of Section 4(f). To equate a preliminary information request in response to a Section 21 petition with expeditious action on high concern

chemicals under Section 6 would make Section 4(f) a nullity and enable EPA to ignore it at will.

6. Supporting this conclusion are three critical points:

- Section 21 merely requires EPA to "initiate an appropriate proceeding" when granting a petition and provides no deadline for carrying out this obligation. Thus, it is a far less prescriptive provision than Section 4(f), which defines the goals of the action EPA must take and the deadline for taking it.

- EPA's limited, voluntary request for information fell far short of "initiat[ing} applicable action" to "prevent or reduce [a serious or widespread risk]" under Section 4(f). If mere information collection could satisfy EPA's non-discretionary duty, it could indefinitely ignore the significant risk it identified under sSection 4(f), leaving the public without meaningful protection. This was clearly not Congress' intent.

- The comprehensive rulemaking provisions of Section 6 define the steps necessary to "initiate applicable action" within the meaning of Section 4(f). Where EPA has conducted a risk evaluation finding an unreasonable risk (as EPA has done for fluorinated containers), Section 6(a) directs that it "shall" adopt a Section 6(a) rule that eliminates the unreasonable risk. Section 6(c) sets a deadline of one year for proposing this rule and two years for finalizing it. The statute nowhere identifies information collection as a required step in the rulemaking process.

7. To support its finding of mootness, the District Court maintained that, if Plaintiff-Appellants prevailed, "the only available remedy would have been a court order requiring EPA to 'initiate applicable action' under [section 6]" because a more extensive order would exceed the court's authority by limiting policy choices committed to agency discretion. JA201-202. Here, however, it is

TSCA itself which directs that the "applicable action" EPA must take is to "prevent or reduce to a sufficient extent" the significant risk triggering Section 4(f). Thus, any order issued by the District Court must be sufficiently prescriptive to assure that EPA carries out this obligation by the deadline set by Congress.

8. In addition to its obligations under Section 4(f), EPA has a non-discretionary duty under the TSCA Section 7 "imminent hazard" provisions. 15 U.S.C. § 2606. Section 7(a)(2) of TSCA specifies that, if EPA "has not made a rule under section [6(a)] immediately effective" as authorized by Section 6(d)(3)(A), it "shall" commence a suit for immediate injunctive relief where the substance at issue presents an "imminent hazard" as defined in Section 7(f). There is no doubt that fluorinated containers meet this definition, which closely tracks the trigger for action under Section 4(f). Nor is there any doubt that EPA has failed to promulgate an "immediately effective" rule for fluorinated containers under Section 6(d).

9. However, the District Court incorrectly read Section 7(a)(2) to impose a mandatory duty only where EPA has already promulgated a Section 6 rule but failed to make it immediately effective. JA203-205. This misconstrued the plain language of the statute, which directs EPA to file an imminent hazard action whenever it has "not made a rule under section [6(a)] of this title immediately

effective." This condition could be satisfied either by the absence of a Section 6(a) rule or by the existence of such a rule which is not immediately effective. To allow citizens' suits only in the latter circumstance would deny judicial relief where district court intervention is most urgent to protect the public. It is implausible that this was Congress' intent.

10. EPA also argued below (and the District Court apparently agreed) that Section 7 does not create a mandatory duty because it contains no deadline for EPA action. However, a statute may create a non-discretionary duty if a deadline is readily ascertainable from other fixed dates or events required by the law. Here, the 180-day deadline in Section 4(f) is a logical timeframe for complying with EPA's mandatory duty under Section 7(a)(2) because both contain remarkably similar triggers for action and Section 7 is one of three TSCA provisions under which EPA may respond to a 4(f) finding.

ARGUMENT

Standard of Review

This Court "review[s] *de novo* a dismissal for lack of subject matter jurisdiction." *Fla. Health Scis. Ctr., Inc. v. Sec'y of Health & Hum. Servs.*, 830 F.3d 515, 518 (D.C. Cir. 2016). The Court has also held that, "[o]n review of a district court's dismissal of a complaint for lack of jurisdiction, we make legal determinations *de novo*." *Am. Nat'l Ins. Co. v. FDIC*, 642 F.3d 1137, 1139 (D.C.

Cir. 2011). Mootness claims are also reviewed *de novo*. *Kifafi v. Hilton Hotels Ret. Plan*, 701 F.3d 718, 724 (D.C. Cir. 2012). More generally, courts of appeals "review *de novo* questions of law raised in dismissals under Rules 12(b)(1) and 12(b)(6)." *N. Cnty. Cmty. All., Inc. v. Salazar*, 573 F.3d 738, 741 (9th Cir. 2009).

I. Plaintiff-Appellants have Associational Standing Based on Current and Anticipated Injuries to Two of Their Senior Staff from Exposure to PFOA in Fluorinated Containers

As the Supreme Court has explained, "the irreducible constitutional minimum of standing contains three elements." *Lujan v. Defenders of Wildlife*, 504 U.S. 555, 560 (1992). "First, the plaintiff must have suffered an injury in fact," i.e., "an invasion of a legally protected interest which is (a) concrete and particularized, . . . and (b) actual or imminent, not conjectural or hypothetical." *Id*. (citations and internal quotation marks omitted). Second, "there must be a causal connection between the injury and the conduct complained of" -- the injury alleged must be "fairly traceable to the challenged action of the defendant." *Id.* (internal quotation marks omitted). Finally, it must be likely that the injury will be redressed by a favorable decision. *Id.* at 561.

Non-profit groups like PEER and CEH can demonstrate standing either in an organizational or associational capacity. The Supreme Court's *Hunt* decision set out three requirements for associational standing: 1) the organization's members would otherwise have standing to sue in their own right, 2) the interests it seeks to

protect are germane to the organization's purpose, and 3) neither the claim asserted nor the relief requested requires the participation of individual members in the lawsuit. 432 U.S. at 343.

The second two requirements are easily met here. The organizational purposes of PEER and CEH include protecting the public from environmental and public health threats. Complaint ¶¶31-36, JA13-16. CEH is dedicated to eliminating or reducing harmful chemicals in air, food, water and everyday products, including PFAS and fluorinated containers. *Id, at* ¶¶25-30, JA12-13. PEER was involved in bringing to light the presence of PFAS in these containers. *Id.* ¶33, JA14. It has worked proactively to increase public knowledge and awareness of this threat, advocating regulatory action and participating in litigation to stop the creation of PFAS during fluorination. *Id.* ¶34, JA14. Spearheading this case is thus a logical outgrowth of PEER and CEH's long-standing organizational purposes.

The claims asserted here do not require the participation of individual PEER and CEH supporters: the issues are not personal to any supporter, but involve legal questions concerning the nature of EPA's non-discretionary duty under TSCA Sections 4(f) and 7. The relief sought is regulatory action by EPA to discharge its non-discretionary duties under TSCA, and this remedy also does not require the involvement of individual supporters.

Finally, the first *Hunt* requirement is met because PEER and CEH's staff and supporters have been harmed and are threatened with future harm by exposure to PFOA in fluorinated containers, and that injury is fairly "traceable" to EPA's failure to comply with Section 4(f) and would be "redressed" by the relief PEER and CEH seek. CEH has approximately 50,000 supporters, as well as Board members and staff, who use products packaged in plastic containers that may be fluorinated. Complaint ¶29, JA13. PEER has thousands of supporters and subscribers to its publications nationwide. *Id.* ¶32, JA14. Its Board members, supporters and staff also use a variety of products packaged in plastic containers that are likely fluorinated. Id. ¶36, JA14-15.

The harm faced by these supporters is epitomized by standing declarations from two senior employees – Dr. Kyla Bennett, PEER's Science Director, and Thomas Fox, CEH's Senior Legislative Counsel. These declarations (presented in an Addendum to this Brief) substantiate their current and anticipated injuries from fluorinated containers, establishing their standing to sue in their own right. As described in their declarations, Dr. Bennett and Mr. Fox have been and remain exposed to PFOA from numerous products distributed in fluorinated plastic containers and are justifiably concerned about continuing and future harms to their health from this exposure.

In *Hunt,* 432 U.S.at 344-45, the Supreme Court relied on an "indicia of membership" test to uphold the standing of a state apple commission to sue on behalf of apple growers who were not its members. Likewise, while PEER and CEH are not traditional membership organizations, they have sufficient "indicia of membership" for standing because their supporters, staff and Boards of Directors have "a sufficient amount of interaction to influence the organization's activities." *Flyers Rights Educ. Fund, Inc. v. United States Dep't of Transp*, 957 F.3d 1359, 1362 (D.C. Cir. 2020).

Based on *Hunt*, lower courts have recognized that organizations have standing to represent the interests of supporters and employees who claim injury from the actions of the defendant based on their responsibilities and roles in the organization. *Air All. Hous. v. United States Chem. & Safety Hazard Investigation Bd.*, 365 F. Supp. 3d 118, 129 (D.D.C. 2019) (finding standing for organization because Board members and the Executive Director exercise a governance function in the organization and basing standing on injury to the Executive Director); *Smith v. Pacific Props. & Dev. Corp.,* 358 F.3d 1097 (9th Cir.2004) (finding standing based on an individual who participated in a program carried out by the organization); *Env't Prot. Info. Ctr. v. Pac. Lumber Co.,* 469 F. Supp. 2d 803, 815 (N.D. Cal. 2007) (standing based on individual who was both an employee and a member). The case for standing is particularly strong here because Dr. Bennett

and Mr. Fox exercise considerable nfluence over their organization's scientific and advocacy work and are supporters as well as staff, and because alleviating the health threats of PFAS is a core PEER and CEH priority.

Dr. Bennett has been exposed to PFOA from drinking water contaminated by a mosquito control pesticide that was packaged in Inhance-fluorinated containers and sprayed over large areas of her community for several years. Bennett Standing Declaration, ¶¶ 17-19, 25-26. She has also used several personal care and household products packaged in fluorinated containers, a riding mower and chain saw equipped with plastic fluorinated fuel tanks, and fluorinated plastic fuel cans. *Id*. ¶¶ 27-34. Dr. Bennett was diagnosed with a hemangioblastoma (a brain tumor) in 2021 and had two brain surgeries. *Id.* ¶¶ 35-40. Her doctors consider it plausible that her tumor was in part due to exposure to PFOA, which studies have linked to brain cancer, and she undergoes regular checkups for signs of a recurrence. Tests of Dr. Bennett's blood have detected elevated levels of PFOA and other PFAS and, despite her efforts to avoid fluorinated plastic products, she is concerned that they are still a source of PFOA exposure. *Id*. ¶¶37, 41.

Mr. Fox and his family breed Cavalier King Charles Spaniels. He is heavily involved in daily care of the dogs, including their feeding, bathing and grooming and cleaning the dog room, kennels, and rest of the house. Fox Standing Declaration, ¶¶ 17-18. During these activities, Mr. Fox has had continuous contact

with plastic containers that are known to be fluorinated from Inhance's marketing and other materials, including cleaning products and grooming supplies for dogs such as shampoos, conditioners and disinfectants. Based on an inventory of large plastic containers of cleaning and grooming products in his possession, Mr. Fox identified 35 such products likely fluorinated by Inhance. *Id.*

Mr. Fox lives on a large property that requires extensive care and upkeep. For this purpose, he regularly uses at least four outdoor products with plastic fuel tanks likely fluorinated by Inhance and refuels these tanks with five-gallon portable plastic canisters also likely to have been fluorinated. *Id*. ¶¶ 2-28. Like Dr. Bennett, Mr. Fox is concerned that his health is being harmed by past, present and future exposure to PFOA and other PFAS but cannot discontinue the use of fluorinated containers because of the cost and other burdens of replacing them and because many of the products he uses lack non-fluorinated alternatives. *Id*. ¶ 29.

The decisions of this Circuit recognize that "[e]nvironmental and health injuries often are purely probabilistic" and to establish standing, plaintiffs must "demonstrate a 'substantial probability' that they will be injured." *Natural Res. Def. Council v. EPA,* 464 F.3d 1, 6 (D.C. Cir. 2006). "Adverse health effects . . . constitute Article III injuries, even if a petitioner merely asserts realistic health concerns instead of providing medical evidence." *Clean Wisconsin v. Env't Prot. Agency,* 964 F.3d 1145, 1156 (D.C. Cir. 2020). *See also Nat. Res. Def. Council v.*

EPA, 755 F.3d 1010, 1016-17 (D.C. Cir. 2014) (finding standing based on declarations of individuals "who are concerned about the [challenged EPA action's] effects on their health and, in some cases, spend less time outdoors on that account").

Here, Dr. Bennett and Mr. Fox have established the requisite "probability of harm" by demonstrating that (i) they have experienced ongoing and substantial exposure to PFOA from fluorinated containers and (ii) EPA itself has determined that any level of PFOA exposure poses a significant risk of cancer and other serious health effects. They have also shown that this risk is directly "traceable" to EPA's failure to prohibit PFAS formation during fluorination and would be "redressed" if the District Court ordered the Agency take action to satisfy its obligations under Section 4(f). This Court should thus uphold PEER and CEH's standing to sue EPA on their behalf.

II. The Burden of Establishing Mootness is a Heavy One

A motion to dismiss for lack of jurisdiction challenges the court's power to hear the case. "[A] federal court's power to hear a case . . . is generally conferred by the basic statutory grants of subject matter jurisdiction, such as 28 U.S.C. § 1331 [federal question jurisdiction] . . . If a plaintiff invoking § 1331 pleads a colorable claim arising under the Constitution or laws of the United States, . . . he invokes federal subject matter jurisdiction, and deficiencies of the claim should be

addressed by the other mechanisms provided by the federal rules." *Holloway v. Pagan River Dockside Seafood*, 669 F.3d 448, 453 (4th Cir. 2012) (internal quotation marks and citation omitted).

When deciding a motion to dismiss, and on appellate review of such a dismissal, the court must "assume the truth of all material factual allegations in the complaint and construe the complaint liberally, granting plaintiff the benefit of all inferences that can be derived from the facts alleged, and upon such facts determine [the] jurisdictional questions." *Am. Nat. Ins. Co. v. FDIC*, 642 F.3d 1137, 1139 (D.C. Cir. 2011) (internal quotation marks and citations omitted).

Here the complaint pleads a colorable claim under TSCA, a law of the United States. The lower court recognized the sufficiency of this claim but then found that it was moot. A defendant bears the burden to demonstrate mootness, and "[t]he burden is a heavy one." *United States v. W.T. Grant Co*., 345 U.S. 629, 633 (1953). "Simply stated, a case is moot when the issues presented are no longer 'live' or the parties lack a legally cognizable interest in the outcome." *County of Los Angeles v. Davis*, 440 U.S. 625, 631 (1979) (quoting *Powell v. McCormack*, 395 U.S. 486, 496 (1979)). Thus, a case is only moot if the court is unable to grant "any effectual relief whatever to the prevailing party." *City of Erie v. Pap's A.M.*, 529 U.S. 277, 287 (2000) (internal citations and quotation marks omitted; emphasis added).

As shown below, the allegations in their Complaint plainly establish that EPA violated its non-discretionary duty under Section 4(f) of TSCA. They also show beyond dispute that EPA's recent actions fail to remedy that violation as required by Section 4(f). Thus, there is an ongoing "case or controversy" that precludes mootness.

III. The Allegations in the Complaint Establish that EPA Failed to Perform its Section 4(f) Duty to "Initiate Action to Prevent or Reduce" the Health Risks of Fluorinated Containers

A. Section 4(f) of TSCA Creates a Non-Discretionary Duty that is Judicially Enforceable under Section 20(a)(2)

Section 20(a)(2) of TSCA, 15 U.S.C. § 2619(a)(2), provides for citizen suits challenging the Administrator's failure to perform any non-discretionary duty under TSCA. A statute imposes a nondiscretionary duty if it "'categorically mandate[s]' that all specified action be taken by a date-certain deadline." *Sierra Club v. Thomas*, 828 F.2d 783, 791 (D.C. Cir. 1987). Moreover, "[o]rdinarily, legislation using 'shall' indicates a mandatory duty." *Anglers Conservation Network v. Pritzker*, 809 F.3d 664, 671 (D.C. Cir. 2016); *United States v. Monsanto,* 491 U.S. 600, 607 (1989) (by using "shall" in a statute, "Congress could not have chosen stronger words to express its intent that forfeiture be mandatory in cases where the statute applied.")

Section 4(f) is such a mandate because it uses the word "shall" both to define the Agency's duty (EPA "*shall* . . . initiate applicable action under section

[5, 6 or 7])" and to impose a deadline for discharging that duty (EPA "*shall"* initiate action to prevent or reduce the risk "within the 180-day period beginning on the date of the receipt of such information.") (Emphasis added). The use of "shall," coupled with an explicit deadline for EPA action leave no doubt that Section 4(f), creates a "duty under [TSCA] which is not discretionary" and therefore is enforceable against the Agency in a suit under section 20(a)(2).

As shown below, construed in favor of Plaintiff-Appellants, the allegations in their Complaint plainly establish that EPA violated its non-discretionary duty under Section 4(f) of TSCA. They also show beyond dispute that EPA's recent actions fail to remedy that violation as required by Section 4(f). Thus, there is an ongoing "case or controversy" that precludes a finding of mootness.

B. By Early 2023, EPA Had Information that PFOA Formed During Fluorination "Presents a Significant Risk of Serious or Widespread Harm" to Health

According to EPA, the "purpose of section 4(f) is to focus the Agency's attention on chemicals that pose potentially high risks to people." 49 Fed. Reg. 21870 (May 23, 1984). As the Agency has said, "[w]hile the terms 'significant risk of serious harm' and 'significant risk of widespread harm' are not defined by TSCA, the language of the statute indicates that both standards reflect attempts to define situations of apparent gravity *Id.*[6]

[6] EPA made three Section 4(f) designations in the 1980s. *See* 48 Fed. Reg. 19078

Applying similar terminology in other laws, courts have held that the "significance" of a risk depends on its nature, duration, and severity and the probability that the potential injury will occur. *School Bd. of Nassau County v. Arline,* 480 U.S. 273, 288 (1987). In its guidance interpreting the reporting requirements in section 8(e) of TSCA, EPA has similarly advised that a "substantial risk of injury" is a "risk of considerable concern because of (a) the seriousness of the effect . . . and (b) the fact or probability of its occurrence." 68 Fed. Reg. 33129, 33138 (June 3, 2003). The guidance presumes that a "substantial risk" is presented by "[a]ny pattern of effects or evidence which reasonably supports the conclusion that the chemical substance or mixture can produce cancer, mutation, birth defects or toxic effects resulting in death, or serious or prolonged incapacitation." *Id.*

To trigger Section 4(f), information need not be definitive or conclusive. Rather, the 180-day clock for action begins to run if there "may be a reasonable basis to conclude" that the substance presents "a significant risk of serious or widespread harm to human beings." In this case, EPA has had such a "reasonable basis" since March 29, 2023, if not earlier.

(April 27, 1983) (Methylenedianiline); 49 Fed. Reg. 845 (January 5, 1984) (1,3-Butadiene); 49 Fed. Reg. 21870 (May 23, 1984) (Formaldehyde). No Section 4(f) designations have been made since then.

EPA began investigating PFAS formation during fluorination in 2020 following testing by PEER and the State of Massachusetts that detected PFAS in mosquito control products packaged in fluorinated containers. During the ensuing three years, it received voluminous information from Inhance in response to two 2021 subpoenas and the comprehensive Significant New Use Notices Inhance submitted in late 2022; conducted three rounds of testing confirming the presence of PFOA and other PFAS in fluorinated containers and their contents; issued a Notice of Violation in 2022 informing Inhance that its PFAS formation violated EPA's 2020 Significant New Use Rule for long-chain PFAS; and filed an enforcement action to enjoin Inhance's ongoing violations in late 2022. By the end of 2022, EPA knew that Inhance fluorinated 200 million containers a year; that PFOA and several other PFAS were consistently present in these containers and their contents; that the containers were used in numerous sectors of the economy, exposing millions of consumers and workers to PFAS; and that these PFAS were released into the environment during the fluorination process, downstream processing and use, and disposal of used containers. [7]

Well before becoming aware of fluorination in 2020, EPA had recognized the risks of PFAS from their extreme persistence, accumulation in people and the environment, and multiple adverse health effects. Starting in 2002, EPA identified

[7] These facts are documented in the Statement of the Case above.

PFOA as an urgent health concern and successfully pushed industry to cease its production in 2015. On March 29, 2023, EPA reiterated these previous findings in its proposed National Primary Drinking Water Regulation for PFOA and five other PFAS, determining that PFOA is "likely to cause cancer (*e.g.,* kidney and liver cancer) and there is no dose below which … [it] is considered safe."[8]

In short, by March 29, 2023 if not earlier, EPA had compelling evidence of PFOA's cancer risk at all dose levels and pervasive PFOA exposure from the annual distribution, use and disposal of 200 million PFOA-contaminated plastic containers. Thus, EPA had a "reasonable basis" to conclude that PFOA formation during fluorination presented a health risk that was "significant" and would cause "serious" and "widespread harm" to humans. If Section 4(f) was not triggered under these circumstances, it is hard to imagine any chemical risk that might qualify.

The case for triggering Section 4(f) was reinforced on December 1, 2023, when EPA issued an order under Section 5(f) of TSCA prohibiting Inhance from producing PFOA and two other PFAS during fluorination. JA128-179. Supported by an extensive risk assessment, JA66-126, the order explicitly determined that these PFAS presented an unreasonable risk of injury to health. JA133-136. In support, EPA emphasized that: "[b]ecause of the persistent and bioaccumulative

[8] 88 Fed. Reg. 18638, 18639 (March 29, 2023).

nature of these PFAS, exposure to each SNUN Chemical Substance will continue over time, long after the immediate exposure associated with their use;" "the identified hazards of PFOA are so significant that there are no safe levels of exposure;" and extensive exposure and environmental release are the inevitable "result of leaching or migration of [PFAS] from fluorinated, plastic storage containers over time into" numerous consumer and industrial products. *Id*.

Thus, the order concluded that EPA "cannot control potential exposures to the SNUN Chemical Substances through means other than a prohibition on the manufacture of these substances." JA135-136. As EPA elaborated, "[g]iven the diverse uses of the products contained in these fluorinated containers, and the fact that leaching can occur throughout the lifecycle of the fluorinated containers, EPA cannot realistically set limits on releases to water, air, and/or land, or mitigate worker, consumer, and general population exposures . . . [and] prevent the PFOA contamination . . . other than prohibiting the PFOA from being manufactured in the first place." JA171.

Because Section 4(f) was triggered at least by March 29, 2023, the 180-day deadline for taking action would have been September 25, 2023. Even if (contrary to the evidence) Section 4(f) was not triggered until EPA's December 1, 2023 order, EPA would have been obligated to take action by May 29, 2024. These dates have long since passed.

C. EPA's Non-Committal Response to Plaintiff-Appellants' Section 21 Petition Fell Short of Satisfying EPA's Mandatory Duty under Section 4(f) and Did Not Render this Case Moot

The lower court recognized that, "once the agency was in possession of information showing that PFOA 'presents a significant risk of serious or widespread harm to human beings,' it faced a nondiscretionary duty to 'initiate applicable action . . . within 180 days.'" JA200. The Court further agreed that, "[t]aking Plaintiffs' allegations as true, EPA's [section 4(f)] duty] arose by March 29, 2023 — which means that it was tardy in its initial order against Inhance (in December 2023) and similarly dragged its feet after the Fifth Circuit vacated its Order" on March 2, 2024. *Id.*

However, the Court then found that two subsequent steps taken by EPA had "initiate[d] applicable action" under Section 4(f) and thus afforded the only relief to which Plaintiffs were entitled: (i) a three-page July 20, 2024 letter "granting" Plaintiffs-Appellants' TSCA Section 21 petition for Section 6(a) rulemaking on fluorinated containers, JA38-41, and (ii) a short September 30, 2024 Federal Register notice (89 Fed. Reg. 79581) requesting information on limited issues EPA deemed relevant to that rulemaking JA42-46. According to the Court, "by kickstarting the information-gathering process," EPA "successfully completed the necessary first step of any rulemaking." JA201. This "rendered moot Plaintiffs' first claim for relief, for which the only available

remedy would have been a court order requiring EPA to take 'applicable action' under section 6." JA202.

As shown below, the District Court's analysis was contrary to the plain language and intent of Section 4(f). To equate a preliminary information request in response to a Section 21 petition with expeditious action to prevent or reduce risks of high concern would make a Section 4(f) a nullity and enable EPA to ignore it at will.

1. EPA's Obligations Under Section 21 Are Far More Limited than its Responsibilities Under Section 4(f)

Section 21(a), 15 U.S.C. § 2620(a), authorizes citizens to file petitions seeking issuance, amendment or repeal of a rule or order under TSCA sections 4, 5, 6 and 8. Under Section 21(b)(3), EPA must "grant or deny" petitions in 90 days. When it grants a petition, Section 21(b)(3) directs that EPA "shall promptly commence an appropriate proceeding." However, no timetable is provided for this "appropriate proceeding" and there is no indication of the steps EPA must take during that proceeding or its scope and objectives.

The Fourth Circuit has held that, when "granting" a Section 21 petition, EPA need not take the actions requested by the petitioner but has considerable discretion over how the goals of the petition should be met and what specific tools in the law should be used to achieve them. *Center for Environmental Health*, 103 F.4th 1027, 1030, 1038-39 (4th Cir. 2024). Thus, in its July 20, 2024 letter "granting"

Plaintiffs-Appellants' Section 21 petition, EPA only said that it "will promptly commence an appropriate proceeding under TSCA Section 6" and "[a]s part of that proceeding . . . request information" about various aspects of fluorination. JA40. The letter did not provide the timetable for this "proceeding" or make any determinations about the health impacts of fluorinated containers beyond noting that they raised a "risk of concern." *Id.* No action to "prevent or reduce" the risk "to a sufficient extent" was initiated, as required under Section 4(f).

By contrast, Section 4(f) explicitly directs EPA to provide health protection against risks of high concern and sets a mandatory deadline to address these risks. The threshold for action under Section 4(f) demands a stronger and more compelling showing of threats to health than Section 21 or other TSCA provisions -- "a significant risk of serious or widespread harm to human beings."[9] Where EPA has information meeting this high standard, Section 4(f) is explicit about the course EPA must follow. Instead of simply "commenc[ing] an appropriate proceeding" as allowed under Section 21, EPA must "initiate applicable action" under one of three regulatory authorities – sections 5, 6 and 7. Moreover, the "applicable action" EPA must take is not open-ended but must accomplish a specific goal: to "prevent or reduce" the significant risk triggering Section 4(f). The levels of risk mitigation

[9] The only comparable provision is Section 7, authorizing imminent hazard actions, which imposes a standard for action remarkably similar to Section 4(f), as discussed below.

that EPA affords must also be "to a sufficient extent," i.e. must achieve a level of health protection commensurate with the nature and severity of the health threat. Finally, rather than allowing EPA to determine the timeframe for taking action, Congress gave it a 180 day deadline (extendable by up to 90 days for "good cause") to meet these obligations.[10]

2. Treating EPA's Limited Information Request as Initiating Applicable Action Would Violate Section 4(f)'s Language and Intent

The District Court believed that EPA's brief September 30, 2024 Federal Register notice (89 Fed. Reg. 79581) was, without more, sufficient to initiate "applicable action" under Section 4(f).[11] JA202. This was incorrect.

The notice did not flesh out the "appropriate proceeding" EPA had previously agreed to conduct under Section 21. Instead, it merely described the Section 21 petition, briefly summarized relevant TSCA provisions, and

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[10] A period of 6-9 months for initiating action would have been unnecessary if EPA could discharge its obligations under Section 4(f) merely by requesting additional information. Thus, the timetable provided by Congress strongly suggests that it expected EPA to propose a Section 6 rule (or take equivalent steps under sections 5 or 7) to "prevent or reduce such risk to a sufficient extent" unless it determined that the risk was "not unreasonable." By giving EPA up to nine months to respond to 4(f) information, Congress signified that it wanted the Agency to have enough time to propose meaningful and substantive risk abatement measures. Indeed, as discussed below, TSCA Section 6(c)(1) sets a one-year deadline for proposing a Section 6(a) rule following a determination of unreasonable risk – a timeframe only three months longer than in Section 4(f).

[11] The notice did not mention Section 4(f) even though EPA was in receipt of Plaintiff-Appellants' 60-day notice letter under TSCA Section 20(b)(2).

requested information on three questions touching on narrow, largely economic issues that EPA claimed it would need to analyze during a Section 6 rulemaking. JA44-45. EPA's notice claimed that this information was "necessary to inform the Agency's path forward with respect to regulation . . . under TSCA section 6." 89 Fed. Reg. at 79583; JA44.[12] However, the notice did not itself purport to initiate rulemaking under Section 6 and neither proposed nor sought comment on Section 6 requirements that would prevent or reduce the risks of the fluorination process. For example, nowhere did EPA address whether PFOA's persistence, bioaccumulation, widespread exposure and serious adverse health effects demonstrated an unreasonable risk and warranted a prohibition on PFAS formation, as determined in EPA's December 1, 2023 Section 5(f) order.

To treat EPA's request for information as sufficient to "initiate applicable action" under TSCA Section 6 would render Section 4(f) toothless in protecting public health. Merely by seeking information that might be relevant to a future Section 6 rulemaking, EPA could indefinitely ignore the significant risk it

[12] The declaration submitted to the lower court by PEER's science director Kyla Bennett demonstrated that the notice was unnecessary because, after its extensive investigation of Inhance, "EPA already has considerable information on all three issues, does not need additional information to propose a section 6 rule banning PFAS formation during fluorination, and is unlikely to obtain additional meaningful information in response to its Federal Register notice." Bennett Declaration ¶ 16, JA192.

identified under Section 4(f), leaving the public without meaningful protection. This is exactly what EPA is doing here.

Congress plainly had a different intent. According to EPA, the "purpose of Section 4(f) is to focus the Agency's attention on chemicals that pose potentially high risks to people . . . [by] ensur[ing] that Agency resources will be immediately devoted to assessing whether action should be initiated to prevent or control the risks." 49 Fed. Reg. at 21870. As the conference report on the 1976 law emphasized, once the Section 4(f) risk threshold is satisfied, "the Administrator shall initiate [applicable] action under section 5, 6, or 7 *to protect against the risk* or publish in the Federal Register a finding that the risk is not unreasonable." H.R. Report No. 94-1679, 94th Cong.2d Sess. (1976) at 62 (emphasis added). In context, the phrase "initiate applicable action" must therefore mean more than collecting information. Instead, it requires concrete and effective measures to "prevent or reduce" a "significant risk of serious or widespread harm." The September 30, 2024 Federal Register did not perform this function.

3. The Rulemaking Requirements in TSCA Section 6 Define the Steps Required to Initiate Applicable Action under Section 4(f)

Section 6 further defines the steps necessary to "initiate applicable action" within the meaning of Section 4(f). Section 6(a) provides that if EPA "determines that . . . the manufacture, processing, distribution in commerce, use, or disposal of

a chemical substance . . . presents an unreasonable risk of injury to health or the environment, the Administrator *shall by rule* … apply one or more of the [enumerated] requirements . . . to the extent necessary so that the chemical substance or mixture no longer presents such [unreasonable] risk" (emphasis added). In this case, EPA's December 1, 2023 Section 5(f) order and risk assessment found that PFOA formation during fluorination presents an unreasonable risk. Thus, the "applicable action" EPA was required to take under Section 6(a) was to propose a "rule" eliminating that risk by imposing one or more of the regulatory restrictions listed in Section 6(a)(1)-(7).[13]

Section 6(c) provides additional direction on the timing and elements of the rulemaking process.. Under section 6(c)(1)(A)-(B), EPA "*shall* propose in the Federal Register a rule . . . not later than 1 year after the date on which the final risk evaluation regarding the chemical substance is published" and "*shall* publish . . . a final rule" not later than one year thereafter. (Emphasis added). Under Section 6(c)(3), EPA's proposed rule must be "in accordance with section 553 of" the Administrative Procedure Act. Thus, EPA had to notify the public of "the time, place, and nature of public rule making proceedings"; "the legal authority under which the rule is proposed"; and "the terms or substance of the proposed rule or a

[13] These requirements include prohibiting or restricting manufacture, distribution and commercial use and public warnings of the risk of injury.

description of the subjects and issues involved." 5 U.S.C § 553(b)(1)–(3); *Stringfellow Memorial Hospital v. Azar,* 317 F.Supp.3d 168, 185 (D.D.C. 2018). TSCA section 6(c)(3) further requires EPA's proposed rule to "stat[e] with particularity the reason for the proposed rule" and "make and publish with the rule the determination [of unreasonable risk] described in subsection (a)." The September 30, 2024 Federal Register notice contained none of these elements and thus failed to satisfy EPA's obligation under Section 6(c)(1) to "propose a rule" within a year of determining an unreasonable risk.

While Section 6(c)(2)(A) and (C) require EPA to analyze and prepare statements on various economic issues relating to its proposed and final rule, the statute does not mention information collection as a required step in the rulemaking process, perhaps assuming that EPA would obtain the data it needs when conducting a risk evaluation in advance of proposing a Section 6(a) rule (as the Agency did here). Given the extensive information collected and analyzed in connection with EPA's SNUR review and risk assessment, it is highly doubtful that additional information collection is needed at all. But even if EPA properly felt it needed additional time for information collection, this would not excuse its failure to meet the Section 4(f) deadline to initiate applicable action under Section 6. "Courts also tend to reject as contrary to the relevant statute agency approaches to rulemaking that sacrifice the timely implementation of the statute in favor of

extensive agency information-gathering and analysis." *Sierra Club v. Johnson,* 444 F.Supp.2d 46, 53-54 (D.D.C. 2006).

In short, the only "applicable action" contemplated under Sections 6(a) and (c) was to propose a rule eliminating the unreasonable risk presented by fluorinated containers. Because EPA's Federal Register notice did not accomplish this task, it failed to discharge EPA's duty under Section 4(f).

D. While EPA May Have Policy Discretion in Carrying Out its 4(f) Obligations, the Court's Remedy Must Be Sufficiently Prescriptive to Assure that EPA Fulfills the Requirements of Section 4(f)

In holding that EPA's information request satisfied Section 4(f), the District Court emphasized that "EPA's sole nondiscretionary duty in § 2603(f) is to 'initiate applicable action' under one of three provisions" and "the only available remedy would have been a court order requiring EPA to 'initiate applicable action' under [section 6]." JA201-202. A more expansive remedy "would thus contravene the statute's requirements, all in the service of inappropriately 'embroil[ing] the Court in an assessment of the substance of EPA's actions or omissions'" (citing *Sierra Club v. Browner*, 130 F. Supp. 2d 78, 90 (D.D.C. 2001))." JA201. As that decision emphasized, "such substantive judicial review is expressly reserved for the appropriate court of appeals." *Id.*

In this case, however, the statute does not merely require EPA to "initiate applicable action." It directs that this "applicable action" must "prevent or reduce

to a sufficient extent" the significant risk triggering Section 4(f). Moreover, as described above, the "applicable action" EPA must take to achieve these goals is explicitly defined in Section 6, which requires proposal and promulgation of a Section 6(a) rule and specifies the deadlines for taking these steps. A court order which merely directed EPA to "initiate applicable action" would fail to address essential elements of EPA's non-discretionary duties under Sections 4(f) and 6, giving it broad license to ignore requirements that Congress spelled out in the statutory text.

Were EPA to undertake a rulemaking under Section 6(a) on fluorinated containers, it would have discretion over the precise restrictions imposed, the timeline for compliance, the availability of exemptions and other aspects of the rule. If Plaintiff-Appellants disagreed with these decisions, their recourse would be through the judicial review mechanism in Section 19(a) of TSCA. However, EPA has not conducted such a rulemaking, and seeks to use limited actions that plainly did not satisfy Section 4(f) and Section 6 to evade accountability for doing what Section 4(f) expressly requires.

Clearly, Section 20(a) authorizes the District Court to direct EPA to discharge these non-discretionary obligations, even if the specifics of any rule EPA ultimately promulgates may be within its policy discretion and reviewable in this Court under section 19 of TSCA. Court orders enforcing mandatory duties have

not just set compliance deadlines but specifically prescribed the actions the Agency must take to perform the non-discretionary duties it has failed to carry out. *E.g., Sierra Club v. Johnson,* 444 F. Supp. 2d at 61; *Sierra Club v. Wheeler,* 330 F. Supp. 3d 407, 423 (D.D.C. 2018). As in these cases, if EPA is in violation of Section 4(f), the order issued by the District Court must be sufficiently prescriptive to assure that EPA fulfills the requirements of the statute by the mandated deadline. A barebones open-ended directive to "initiate applicable action" is plainly not enough.

IV. Plaintiff-Appellants' Complaint States a Claim that EPA Had a Mandatory Duty to File a Section 7 Action Against Inhance

A. EPA Must File a Section 7 Action if the Evidence Demonstrates an Imminent Hazard and EPA Has Failed to Adopt an Immediately Effective Section 6 Rule

Section 7(a) of TSCA, 15 U.S.C. § 2606, authorizes EPA to file suit "against any person who manufactures, processes, distributes in commerce, or uses, or disposes of, an imminently hazardous chemical substance or mixture." Under Section 7(a)(2) of TSCA, if EPA "has not made a rule under section [6(a)] immediately effective" as authorized by Section 6(d)(3)(A), it "shall" commence a suit for immediate injunctive relief where the substance at issue is "imminently hazardous." Because TSCA states that such suits "shall" be brought for "imminently hazardous" chemicals, filing these actions is a non-discretionary duty of EPA and is enforceable in citizens' suits under TSCA Section 20(a)(2).

The District Judge, however, found that no non-discretionary duty ever arose because "the apparent textual predicate of such an obligation is the existence of a [Section 6] rule in the first place." As he elaborated, "[o]nly then, and only once such a rule had not been made 'immediately effective,' could any duty arise under § 2606. Absent a rulemaking, there is nothing to be made "immediately effective" and consequently no obligation under [section 7(a)(2)]." JA202-203.

This reading conflicts with the plain meaning of the statute. Nowhere does Section 7(a)(2) state that EPA only has a duty to file a Section 7 action if it has already issued a Section 6(a) rule. Rather, that duty is triggered where EPA has "not made a rule under section [6(a)] of this title immediately effective." This condition could be satisfied either by the absence of a Section 6(a) rule or by the existence of such a rule which is not immediately effective. To conclude that only the latter circumstance imposes a non-discretionary duty is not only contrary to the statutory language but contradicts the clear intent of TSCA's imminent hazard authority.

The text and legislative history of TSCA explicitly confirm Congress' desire to authorize citizens to compel EPA to file imminent hazard cases where it fails to act in the face of a serious and urgent threat to health. The pre-suit notification requirements for suits to enforce non-discretionary duties under Section 20(b)(2) refer specifically to the "failure of the Administrator to file an

action under section 7." They also shorten the pre-suit waiting period for suits to compel such actions to 10 days rather than the 60 days required for other TSCA mandatory duty claims. It is thus apparent that Congress attached particular urgency to expeditious action under Section 7 and wanted courts to have jurisdiction over such cases as soon as possible. The Conference Report for the 1976 law explicitly confirms EPA's non-discretionary duty to bring imminent hazard actions where warranted:

> If the Administrator has not used the authority provided in section 6(d)(2)(A)(i) to make a section 6 (a) rule immediately effective in order to protect against an imminently hazardous substance or mixture, *the Administrator must bring an action under section 7. The conferees have imposed such a nondiscretionary duty upon the Administrator to insure that protection is provided against imminently hazardous substances, mixtures, and articles containing such substances and mixtures. (*Emphasis added)

H.R. Report No. 94-1679 at 78.

The District Judge's constricting interpretation of EPA's non-discretionary duty flies in the face of this legislative intent. It would subvert TSCA's purposes if EPA had a duty to bring a Section 7 action when a Section 6(a) rulemaking has already occurred but not where the Agency has failed to take any action at all against an imminent hazard to health. In the former situation, EPA would actually be affording some protection against the hazard, but in the latter it would be ignoring it entirely. It is implausible that Congress wanted to deny judicial relief in the very circumstance where district court intervention is most urgent to protect the

public.[14] Accordingly, the Court should interpret TSCA to authorize courts to enforce Section 7(a)(2) in the absence of an immediately effective rule under Section 6(d)(3)(A), whether a Section 6 rule has been promulgated or not.

B. The Lack of a Specific Deadline in Section 7 Does Not Bar Judicial Action Where Congress Intended to Create a Non-Discretionary Duty and a Deadline Can be Inferred from Related TSCA Provisions

EPA also argued below that Section 7 does not create a mandatory duty because it contains no date-certain deadline by which EPA must take specified action. However, "[a] statute may create a non-discretionary duty by . . . *providing a deadline that is 'readily-ascertainable by reference to some other fixed date or event.'' Appalachian Voices v. McCarthy,* 989 F. Supp. 2d 30, 54 (D.D.C. 2013) (emphasis added).(citation omitted). *See also Infracost Inc. v. Blinken,* 732 F. Supp.

[14] The District Court sought to explain this bizarre result on the ground that "[t]he regulatory paradigm thus appears to be one that broadly leaves to EPA the decision of whether to file an imminent-hazard suit in any given instance" except where EPA has promulgated a Section 6 rule but not made it immediately effective. JA204. However, as noted above, TSCA's legislative history confirms that Congress wanted effective citizens' enforcement "to insure that protection is provided against imminently hazardous substances." This contradicts the lower court's assumption that TSCA vests broad discretion in EPA to decide whether to file imminent hazard cases, with a minimal role for citizen's enforcement. According to the lower court, if citizens' enforcement were broader in scope, "EPA [would need] to file suit under § 2606(a)(2) any time it finds an imminent hazard, so long as no rule had yet been promulgated to address it." JA204-205. But the standard in Section 7(f) for finding an imminent hazard connotes a high and urgent level of risk and it would be unsurprising for Congress to provide for citizen's enforcement in any case where this high standard has been met but EPA has failed to take any action.

3d 1240, 1252 (S.D. Cal. 2024) ("a mandatory duty to act may exist without a mandatory deadline").

The District Judge expressed "doubt" that a mandatory deadline for filing an imminent hazard suit could be ascertained from other TSCA provisions. JA203. However, an obvious guidepost is Section 4(f), under which initiating action under Section 7 is one of three allowable statutory mechanisms for addressing a "significant risk of serious or widespread harm." This Section 4(f) trigger is remarkably similar in wording to the definition of "imminently hazardous chemical substance or mixture" in Section 7(f). Thus, Congress would well have viewed the 180-day deadline for initiating action on 4(f) chemicals as a logical timeframe for complying with EPA's non-discretionary duty to file an imminent hazard action under Section 7(a)(2). The Court should therefore hold that this deadline applies in citizens' suits seeking relief for violations of this duty.

C. Plaintiffs-Appellants' Complaint Alleges Facts that Demonstrate a Mandatory Duty under Section 7(a)(2) in This Case

Section 7(f) defines an "imminently hazardous chemical substance" as one "which presents an imminent and unreasonable risk of serious or widespread injury to health or the environment" and "is likely to result in such injury to health or the environment before a final rule under section 2605 of this title can protect against such risk." Since Section 4(f) of TSCA also requires evidence of a "risk of serious or widespread injury to health," information meeting the 4(f) risk

threshold would warrant a Section 7 suit if it can also be demonstrated that the risk is imminent.[15]

This is the case here because, as described in Plaintiff-Appellants' Complaint and discussed above, EPA has found that PFOA is a human carcinogen which is not safe at any dose, is persistent and builds up in human blood, and puts millions of people at risk because of their exposure to fluorinated containers. The Conference Report for the 1976 law instructs that, "while the unreasonable risk of injury must be imminent, the physical manifestations of the injury itself need not be. Rather, an imminent hazard may be found at any point in the chain of events which may ultimately result in injury to health or the environment. . . . The conferees intend that action under the imminent hazard action be able to occur early enough to prevent the final injury from materializing." H.R. Report No. 94-1679 at 78.

Here too, the risks from fluorinated containers are "imminent" because exposure to PFAS in these containers will initiate a "chain of events" that will later lead to serious and widespread harm from cancer and other health effects caused by PFOA.

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[15] Because of the imminence of the risk, the Section 21 petition filed by Plaintiff-Appellants and five other groups requested that EPA issue an immediately effective rule under section 6(d)(3)(A)(i)(I), a request that EPA ignored. JA62-63. The wording of this provision, like that of Section 7(f), requires a showing that the chemical at issue "is likely to result in an unreasonable risk of serious or widespread injury to health or the environment before" a rule promulgated under the normal Section 6(a) rulemaking process could become effective.

In sum, the allegations in plaintiffs' Complaint demonstrate both an "imminent hazard" and a non-discretionary duty by EPA to file a Section 7 suit to address that hazard. Accordingly, the District Court's dismissal of Plaintiff-Appellants' claim that EPA failed to perform its non-discretionary duty under Section 7 must be reversed.

CONCLUSION

The District Court's order of dismissal should be reversed and the case should be remanded for further proceedings.

Respectfully submitted,

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CERTIFICATE OF COMPLIANCE

I certify that this Brief filing complies with the word limit of Fed. R. App. P. 27(d)(2)(A) because it contains 12,849 words, excluding the parts of the filing exempted by Fed.R. App. P. 32(f). This complies with the typeface and type style requirements of Fed. R. App. P. 32(a)(5) and (6) because it was prepared in a proportionately spaced typeface using Microsoft Word in Times New Roman 14-point font.

/s/Robert M. Sussman
Robert M. Sussman

CERTIFICATE OF SERVICE

I hereby certify that on June 23, 2025, I electronically filed the foregoing Opening Brief with the Clerk of the Court for the United States Court of Appeals for the District of Columbia Circuit by using the CM/ECF system. The participants in the case are registered CM/ECF users and service will be accomplished by the CM/ECF system.

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RELEVANT PROVISIONS OF TOXIC SUBSTANCES CONTROL ACT

15 U.S.C. § 2603(f)

§2603. Testing of chemical substances and mixtures

. . . . . .

(f) Required actions

Upon the receipt of—

(1) any information required to be submitted under this chapter, or

(2) any other information available to the Administrator,

which indicates to the Administrator that there may be a reasonable basis to conclude that a chemical substance or mixture presents a significant risk of serious or widespread harm to human beings, the Administrator shall, within the 180-day period beginning on the date of the receipt of such information, initiate applicable action under section 2604, 2605, or 2606 of this title to prevent or reduce to a sufficient extent such risk or publish in the Federal Register a finding, made without consideration of costs or other nonrisk factors, that such risk is not unreasonable. For good cause shown the Administrator may extend such period for an additional period of not more than 90 days. The Administrator shall publish in the Federal Register notice of any such extension and the reasons therefor. A finding by the Administrator that a risk is not unreasonable shall be considered agency action for purposes of judicial review under chapter 7 of title 5. This subsection shall not take effect until two years after January 1, 1977.

15 U.S.C. § 2604(a) and (f)

§2604. Manufacturing and processing notices

(a) In general

(1)(A) Except as provided in subparagraph (B) of this paragraph and subsection (h), no person may—

(i) manufacture a new chemical substance on or after the 30th day after the date on which the Administrator first publishes the list required by section 2607(b) of this title, or

(ii) manufacture or process any chemical substance for a use which the Administrator has determined, in accordance with paragraph (2), is a significant new use.

(B) A person may take the actions described in subparagraph (A) if—

(i) such person submits to the Administrator, at least 90 days before such manufacture or processing, a notice, in accordance with subsection (d), of such person's intention to manufacture or process such substance and such person complies with any applicable requirement of, or imposed pursuant to, subsection (b), (e), or (f); and

(ii) the Administrator—

(I) conducts a review of the notice; and

(II) makes a determination under subparagraph (A), (B), or (C) of paragraph (3) and takes the actions required in association with that determination under such subparagraph within the applicable review period.

(2) A determination by the Administrator that a use of a chemical substance is a significant new use with respect to which notification is required under paragraph (1) shall be made by a rule promulgated after a consideration of all relevant factors, including—

(A) the projected volume of manufacturing and processing of a chemical substance,

(B) the extent to which a use changes the type or form of exposure of human beings or the environment to a chemical substance,

(C) the extent to which a use increases the magnitude and duration of exposure of human beings or the environment to a chemical substance, and

(D) the reasonably anticipated manner and methods of manufacturing, processing, distribution in commerce, and disposal of a chemical substance.

(3) Review and determination.—Within the applicable review period, subject to section 2617 of this title, the Administrator shall review such notice and determine—

(A) that the relevant chemical substance or significant new use presents an unreasonable risk of injury to health or the environment, without consideration of costs or other nonrisk factors, including an unreasonable risk to a potentially exposed or susceptible subpopulation identified as relevant by the Administrator under the conditions of use, in which case the Administrator shall take the actions required under subsection (f);

(B) that—

(i) the information available to the Administrator is insufficient to permit a reasoned evaluation of the health and environmental effects of the relevant chemical substance or significant new use; or

(ii)(I) in the absence of sufficient information to permit the Administrator to make such an evaluation, the manufacture, processing, distribution in commerce, use, or disposal of such substance, or any combination of such activities, may present an unreasonable risk of injury to health or the environment, without consideration of costs or other nonrisk factors, including an unreasonable risk to a potentially exposed or susceptible subpopulation identified as relevant by the Administrator; or

(II) such substance is or will be produced in substantial quantities, and such substance either enters or may reasonably be anticipated to enter the environment in substantial quantities or there is or may be significant or substantial human exposure to the substance,

in which case the Administrator shall take the actions required under subsection (e); or

(C) that the relevant chemical substance or significant new use is not likely to present an unreasonable risk of injury to health or the environment, without consideration of costs or other nonrisk factors, including an unreasonable risk to a potentially exposed or susceptible subpopulation identified as relevant by the Administrator under the conditions of use, in which case the submitter of the notice may commence manufacture of the chemical substance or manufacture or processing for a significant new use.

(4) Failure to render determination.—

(A) Failure to render determination.—If the Administrator fails to make a determination on a notice under paragraph (3) by the end of the applicable review period and the notice has not been withdrawn by the submitter, the Administrator shall refund to the submitter all applicable fees charged to the submitter for review of the notice pursuant to section 2625(b) of this title, and the Administrator shall not be relieved of any requirement to make such determination.

(B) Limitations.—(i) A refund of applicable fees under subparagraph (A) shall not be made if the Administrator certifies that the submitter has not provided information required under subsection (b) or has otherwise unduly delayed the process such that the Administrator is unable to render a determination within the applicable review period.

(ii) A failure of the Administrator to render a decision shall not be deemed to constitute a withdrawal of the notice.

(iii) Nothing in this paragraph shall be construed as relieving the Administrator or the submitter of the notice from any requirement of this section

(5) Article consideration.—The Administrator may require notification under this section for the import or processing of a chemical substance as part of an article or category of articles under paragraph (1)(A)(ii) if the Administrator makes an affirmative finding in a rule under paragraph (2) that the reasonable potential for exposure to the chemical substance through the article or category of articles subject to the rule justifies notification.

. . . . . .

(f) Protection against unreasonable risks

(1) If the Administrator determines that a chemical substance or significant new use with respect to which notice is required by subsection (a) presents an unreasonable risk of injury to health or environment, without consideration of costs or other nonrisk factors, including an unreasonable risk to a potentially exposed subpopulation identified as relevant by the Administrator under the conditions of use, the Administrator shall, before the expiration of the applicable review period, take the action authorized by paragraph (2) or (3) to the extent necessary to protect against such risk.

(2) The Administrator may issue a proposed rule under section 2605(a) of this title to apply to a chemical substance with respect to which a finding was made under paragraph (1)—

(A) a requirement limiting the amount of such substance which may be manufactured, processed, or distributed in commerce,

(B) a requirement described in paragraph (2), (3), (4), (5), (6), or (7) of section 2605(a) of this title, or

(C) any combination of the requirements referred to in subparagraph (B).

Such a proposed rule shall be effective upon its publication in the Federal Register. Section 2605(d)(3)(B) of this title shall apply with respect to such rule.

(3)(A) The Administrator may issue an order to prohibit or limit the manufacture, processing, or distribution in commerce of a substance with respect to which a finding was made under paragraph (1). Such order shall take effect on the expiration of the applicable review period.

(B) The provisions of subparagraph (B) of subsection (e)(1) shall apply with respect to an order issued under subparagraph (A).

(4) Treatment of nonconforming uses.—Not later than 90 days after taking an action under paragraph (2) or (3) or issuing an order under subsection (e) relating to a chemical substance with respect to which the Administrator has made a determination under subsection (a)(3)(A) or (B), the Administrator shall consider whether to promulgate a rule pursuant to subsection (a)(2) that identifies as a significant new use any manufacturing, processing, use, distribution in commerce, or disposal of the chemical substance that does not conform to the restrictions imposed by the action or order, and, as applicable, initiate such a rulemaking or publish a statement describing the reasons of the Administrator for not initiating such a rulemaking.

(5) Workplace exposures.—To the extent practicable, the Administrator shall consult with the Assistant Secretary of Labor for Occupational Safety and Health prior to adopting any prohibition or other restriction relating to a chemical substance with respect to which the Administrator has made a determination under subsection (a)(3)(A) or (B) to address workplace exposures.

15 U.S.C. § 2605(a), (c) and (d)

§2605. Prioritization, risk evaluation, and regulation of chemical substances and mixtures

(a) Scope of regulation

If the Administrator determines in accordance with subsection (b)(4)(A) that the manufacture, processing, distribution in commerce, use, or disposal of a chemical substance or mixture, or that any combination of such activities, presents an unreasonable risk of injury to health or the environment, the Administrator shall by rule and subject to section 2617 of this title, and in accordance with subsection (c)(2), apply one or more of the following requirements to such substance or mixture to the extent necessary so that the chemical substance or mixture no longer presents such risk:

(1) A requirement (A) prohibiting or otherwise restricting the manufacturing, processing, or distribution in commerce of such substance or mixture, or (B) limiting the amount of such substance or mixture which may be manufactured, processed, or distributed in commerce.

(2) A requirement—

(A) prohibiting or otherwise restricting the manufacture, processing, or distribution in commerce of such substance or mixture for (i) a particular use or (ii) a particular use in a concentration in excess of a level specified by the Administrator in the rule imposing the requirement, or

(B) limiting the amount of such substance or mixture which may be manufactured, processed, or distributed in commerce for (i) a particular use or (ii) a particular use in a concentration in excess of a level specified by the Administrator in the rule imposing the requirement.

(3) A requirement that such substance or mixture or any article containing such substance or mixture be marked with or accompanied by clear and adequate minimum warnings and instructions with respect to its use, distribution in commerce, or disposal or with respect to any combination of such activities. The form and content of such minimum warnings and instructions shall be prescribed by the Administrator.

(4) A requirement that manufacturers and processors of such substance or mixture make and retain records of the processes used to manufacture or process such substance or mixture or monitor or conduct tests which are reasonable and necessary to assure compliance with the requirements of any rule applicable under this subsection.

(5) A requirement prohibiting or otherwise regulating any manner or method of commercial use of such substance or mixture.

(6)(A) A requirement prohibiting or otherwise regulating any manner or method of disposal of such substance or mixture, or of any article containing such substance or mixture, by its manufacturer or processor or by any other person who uses, or disposes of, it for commercial purposes.

(B) A requirement under subparagraph (A) may not require any person to take any action which would be in violation of any law or requirement of, or in effect for, a State or political subdivision, and shall require each person subject to it to notify each State and political subdivision in which a required disposal may occur of such disposal.

(7) A requirement directing manufacturers or processors of such substance or mixture (A) to give notice of such determination to distributors in commerce of such substance or mixture and, to the extent reasonably ascertainable, to other persons in possession of such substance or mixture or exposed to such substance or mixture, (B) to give public notice of

such determination, and (C) to replace or repurchase such substance or mixture as elected by the person to which the requirement is directed.

Any requirement (or combination of requirements) imposed under this subsection may be limited in application to specified geographic areas.

. . . . . .

(c) Promulgation of subsection (a) rules

(1) Deadlines

If the Administrator determines that a chemical substance presents an unreasonable risk of injury to health or the environment in accordance with subsection (b)(4)(A), the Administrator—

(A) shall propose in the Federal Register a rule under subsection (a) for the chemical substance not later than 1 year after the date on which the final risk evaluation regarding the chemical substance is published;

(B) shall publish in the Federal Register a final rule not later than 2 years after the date on which the final risk evaluation regarding the chemical substance is published; and

(C) may extend the deadlines under this paragraph for not more than 2 years, subject to the condition that the aggregate length of extensions under this subparagraph and subsection (b)(4)(G)(ii) does not exceed 2 years, and subject to the limitation that the Administrator may not extend a deadline for the publication of a proposed or final rule regarding a chemical substance drawn from the 2014 update of the TSCA Work Plan for Chemical Assessments or a chemical substance that, with respect to persistence and bioaccumulation, scores high for 1 and either high or moderate for the other, pursuant to the TSCA Work Plan Chemicals Methods Document published by the Administrator in February 2012 (or a successor scoring system), without adequate public justification that demonstrates, following a review of the information reasonably available to the Administrator, that the Administrator cannot complete the proposed or final rule without additional information regarding the chemical substance.

(2) Requirements for rule

(A) Statement of effects

In proposing and promulgating a rule under subsection (a) with respect to a chemical substance or mixture, the Administrator shall consider and publish a statement based on reasonably available information with respect to—

(i) the effects of the chemical substance or mixture on health and the magnitude of the exposure of human beings to the chemical substance or mixture;

(ii) the effects of the chemical substance or mixture on the environment and the magnitude of the exposure of the environment to such substance or mixture;

(iii) the benefits of the chemical substance or mixture for various uses; and

(iv) the reasonably ascertainable economic consequences of the rule, including consideration of—

(I) the likely effect of the rule on the national economy, small business, technological innovation, the environment, and public health;

(II) the costs and benefits of the proposed and final regulatory action and of the 1 or more primary alternative regulatory actions considered by the Administrator; and

(III) the cost effectiveness of the proposed regulatory action and of the 1 or more primary alternative regulatory actions considered by the Administrator.

(B) Selecting requirements

In selecting among prohibitions and other restrictions, the Administrator shall factor in, to the extent practicable, the considerations under subparagraph (A) in accordance with subsection (a).

(C) Consideration of alternatives

Based on the information published under subparagraph (A), in deciding whether to prohibit or restrict in a manner that substantially prevents a specific condition of use of a chemical substance or mixture, and in setting an appropriate transition period for such action, the Administrator shall consider, to the extent practicable, whether technically and economically feasible alternatives that benefit health or the environment, compared to the use so proposed to be prohibited or restricted, will be reasonably available as a substitute when the proposed prohibition or other restriction takes effect.

(D) Replacement parts

(i) In general

The Administrator shall exempt replacement parts for complex durable goods and complex consumer goods that are designed prior to the date of publication in the Federal Register of the rule under subsection (a), unless the Administrator finds that such replacement parts contribute significantly to the risk, identified in a risk evaluation conducted under subsection (b)(4)(A), to the general population or to an identified potentially exposed or susceptible subpopulation.

(ii) Definitions

In this subparagraph—

(I) the term "complex consumer goods" means electronic or mechanical devices composed of multiple manufactured components, with an intended useful life of 3 or more years, where the product is typically not consumed, destroyed, or discarded after a single use, and the components of which would be impracticable to redesign or replace; and

(II) the term "complex durable goods" means manufactured goods composed of 100 or more manufactured components, with an intended useful life of 5 or more years, where the product is typically not consumed, destroyed, or discarded after a single use.

(E) Articles

In selecting among prohibitions and other restrictions, the Administrator shall apply such prohibitions or other restrictions to an article or category of articles containing the chemical substance or mixture only to the extent necessary to address the identified risks from exposure to the chemical substance or mixture from the article or category of articles so that the substance or mixture does not present an unreasonable risk of injury to health or the environment identified in the risk evaluation conducted in accordance with subsection (b)(4)(A).

(3) Procedures

When prescribing a rule under subsection (a) the Administrator shall proceed in accordance with section 553 of title 5 (without regard to any reference in such section to sections 556 and 557 of such title), and shall also—

(A) publish a notice of proposed rulemaking stating with particularity the reason for the proposed rule;

(B) allow interested persons to submit written data, views, and arguments, and make all such submissions publicly available;

(C) promulgate a final rule based on the matter in the rulemaking record; and
(D) make and publish with the rule the determination described in subsection (a).

. . . . . .

(d) Effective date

(1) In general.—In any rule under subsection (a), the Administrator shall—

(A) specify the date on which it shall take effect, which date shall be as soon as practicable;

(B) except as provided in subparagraphs (C) and (D), specify mandatory compliance dates for all of the requirements under a rule under subsection (a), which shall be as soon as practicable, but not later than 5 years after the date of promulgation of the rule, except in a case of a use exempted under subsection (g);

(C) specify mandatory compliance dates for the start of ban or phase-out requirements under a rule under subsection (a), which shall be as soon as practicable, but not later than 5 years after the date of promulgation of the rule, except in the case of a use exempted under subsection (g);

(D) specify mandatory compliance dates for full implementation of ban or phase-out requirements under a rule under subsection (a), which shall be as soon as practicable; and

(E) provide for a reasonable transition period.

(2) Variability.—As determined by the Administrator, the compliance dates established under paragraph (1) may vary for different affected persons.

(3)(A) The Administrator may declare a proposed rule under subsection (a) to be effective, and compliance with the proposed requirements to be mandatory, upon publication in the Federal Register of the proposed rule and until the compliance dates applicable to such requirements in a final rule promulgated under section 2605(a) of this title or until the Administrator revokes such proposed rule, in accordance with subparagraph (B), if—

(i) the Administrator determines that—

(I) the manufacture, processing, distribution in commerce, use, or disposal of the chemical substance or mixture subject to such proposed rule or any combination of such activities is likely to result in an unreasonable risk of serious or widespread injury to health or the environment before such effective date without consideration of costs or other non-risk factors; and

(II) making such proposed rule so effective is necessary to protect the public interest; and

(ii) in the case of a proposed rule to prohibit the manufacture, processing, or distribution of a chemical substance or mixture because of the risk determined under clause (i)(I), a court has in an action under section 2606 of this title granted relief with respect to such risk associated with such substance or mixture.

Such a proposed rule which is made so effective shall not, for purposes of judicial review, be considered final agency action.

(B) If the Administrator makes a proposed rule effective upon its publication in the Federal Register, the Administrator shall, as expeditiously as possible, give interested persons prompt notice of such action in accordance with subsection (c), and either promulgate such rule (as proposed or with modifications) or revoke it.

15 U.S.C. § 2606

§2606. Imminent hazards

(a) Actions authorized and required

(1) The Administrator may commence a civil action in an appropriate district court of the United States—

(A) for seizure of an imminently hazardous chemical substance or mixture or any article containing such a substance or mixture,

(B) for relief (as authorized by subsection (b)) against any person who manufactures, processes, distributes in commerce, or uses, or disposes of, an imminently hazardous chemical substance or mixture or any article containing such a substance or mixture, or

(C) for both such seizure and relief.

A civil action may be commenced under this paragraph notwithstanding the existence of a determination under section 2604 or 2605 of this title, a rule under section 2603, 2604, or 2605 of this title or subchapter IV, an order under section 2603, 2604, or 2605 of this title or subchapter IV, or a consent agreement under section 2603 of this title, and notwithstanding the pendency of any administrative or judicial proceeding under any provision of this chapter.

(2) If the Administrator has not made a rule under section 2605(a) of this title immediately effective (as authorized by section 2605(d)(3)(A)(i) of this title) with respect to an imminently hazardous chemical substance or mixture, the Administrator shall commence in a district court of the United States with respect to such substance or mixture or article containing such substance or mixture a civil action described in subparagraph (A), (B), or (C) of paragraph (1).

(b) Relief authorized

(1) The district court of the United States in which an action under subsection (a) is brought shall have jurisdiction to grant such temporary or permanent relief as may be necessary to protect health or the environment from the unreasonable risk (as identified by the Administrator without consideration of costs or other nonrisk factors) associated with the chemical substance, mixture, or article involved in such action.

(2) In the case of an action under subsection (a) brought against a person who manufactures, processes, or distributes in commerce a chemical substance or mixture or an article containing a chemical substance or mixture, the relief authorized by paragraph (1) may include the issuance of a mandatory order requiring (A) in the case of purchasers of such substance, mixture, or article known to the defendant, notification to such purchasers of the risk associated with it; (B) public notice of such risk; (C) recall; (D) the replacement or repurchase of such substance, mixture, or article; or (E) any combination of the actions described in the preceding clauses.

(3) In the case of an action under subsection (a) against a chemical substance, mixture, or article, such substance, mixture, or article may be proceeded against by process of libel for its seizure and condemnation. Proceedings in such an action shall conform as nearly as possible to proceedings in rem in admiralty.

(c) Venue and consolidation

(1)(A) An action under subsection (a) against a person who manufactures, processes, or distributes a chemical substance or mixture or an article containing a chemical substance or mixture may be brought in the United States District Court for the District of Columbia or for any judicial district in which any of the defendants is found, resides, or transacts business; and process in such an action may be served on a defendant in any other district in which such defendant resides or may be found. An action under subsection (a) against a chemical

substance, mixture, or article may be brought in any United States district court within the jurisdiction of which the substance, mixture, or article is found.

(B) In determining the judicial district in which an action may be brought under subsection (a) in instances in which such action may be brought in more than one judicial district, the Administrator shall take into account the convenience of the parties.

(C) Subpeonas [1] requiring attendance of witnesses in an action brought under subsection (a) may be served in any judicial district.

(2) Whenever proceedings under subsection (a) involving identical chemical substances, mixtures, or articles are pending in courts in two or more judicial districts, they shall be consolidated for trial by order of any such court upon application reasonably made by any party in interest, upon notice to all parties in interest.

(d) Action under section 2605

Where appropriate, concurrently with the filing of an action under subsection (a) or as soon thereafter as may be practicable, the Administrator shall initiate a proceeding for the promulgation of a rule under section 2605(a) of this title.

(e) Representation

Notwithstanding any other provision of law, in any action under subsection (a), the Administrator may direct attorneys of the Environmental Protection Agency to appear and represent the Administrator in such an action.

(f) "Imminently hazardous chemical substance or mixture" defined

For the purposes of subsection (a), the term "imminently hazardous chemical substance or mixture" means a chemical substance or mixture which presents an imminent and unreasonable risk of serious or widespread injury to health or the environment, without consideration of costs or other nonrisk factors. Such a risk to health or the environment shall be considered imminent if it is shown that the manufacture, processing, distribution in commerce, use, or disposal of the chemical substance or mixture, or that any combination of such activities, is likely to result in such injury to health or the environment before a final rule under section 2605 of this title can protect against such risk.

15 U.S.C. § 2619

§2619. Citizens' civil actions

(a) In general

Except as provided in subsection (b), any person may commence a civil action—

(1) against any person (including (A) the United States, and (B) any other governmental instrumentality or agency to the extent permitted by the eleventh amendment to the Constitution) who is alleged to be in violation of this chapter or any rule promulgated under section 2603, 2604, or 2605 of this title, or subchapter II or IV, or order issued under section 2603 or 2604 of this title or subchapter II or IV to restrain such violation, or

(2) against the Administrator to compel the Administrator to perform any act or duty under this chapter which is not discretionary.

Any civil action under paragraph (1) shall be brought in the United States district court for the district in which the alleged violation occurred or in which the defendant resides or in which the defendant's principal place of business is located. Any action brought under paragraph (2) shall be brought in the United States District Court for the District of Columbia, or the United States

district court for the judicial district in which the plaintiff is domiciled. The district courts of the United States shall have jurisdiction over suits brought under this section, without regard to the amount in controversy or the citizenship of the parties. In any civil action under this subsection process may be served on a defendant in any judicial district in which the defendant resides or may be found and subpoenas for witnesses may be served in any judicial district.

(b) Limitation

No civil action may be commenced—

(1) under subsection (a)(1) to restrain a violation of this chapter or rule or order under this chapter—

(A) before the expiration of 60 days after the plaintiff has given notice of such violation (i) to the Administrator, and (ii) to the person who is alleged to have committed such violation, or

(B) if the Administrator has commenced and is diligently prosecuting a proceeding for the issuance of an order under section 2615(a)(2) of this title to require compliance with this chapter or with such rule or order or if the Attorney General has commenced and is diligently prosecuting a civil action in a court of the United States to require compliance with this chapter or with such rule or order, but if such proceeding or civil action is commenced after the giving of notice, any person giving such notice may intervene as a matter of right in such proceeding or action;

(2) under subsection (a)(2) before the expiration of 60 days after the plaintiff has given notice to the Administrator of the alleged failure of the Administrator to perform an act or duty which is the basis for such action or, in the case of an action under such subsection for the failure of the Administrator to file an action under section 2606 of this title, before the expiration of ten days after such notification, except that no prior notification shall be required in the case of a civil action brought to compel a decision by the Administrator pursuant to section 2617(f)(3)(B) of this title; or

(3) in the case of a civil action brought to compel a decision by the Administrator pursuant to section 2617(f)(3)(B) of this title, after the date that is 60 days after the deadline specified in section 2617(f)(3)(B) of this title.

Notice under this subsection shall be given in such manner as the Administrator shall prescribe by rule.

(c) General

(1) In any action under this section, the Administrator, if not a party, may intervene as a matter of right.

(2) The court, in issuing any final order in any action brought pursuant to subsection (a), may award costs of suit and reasonable fees for attorneys and expert witnesses if the court determines that such an award is appropriate. Any court, in issuing its decision in an action brought to review such an order, may award costs of suit and reasonable fees for attorneys if the court determines that such an award is appropriate.

(3) Nothing in this section shall restrict any right which any person (or class of persons) may have under any statute or common law to seek enforcement of this chapter or any rule or order under this chapter or to seek any other relief.

(d) Consolidation

When two or more civil actions brought under subsection (a) involving the same defendant and the same issues or violations are pending in two or more judicial districts, such pending actions, upon application of such defendants to such actions which is made to a court in which any such action is brought, may, if such court in its discretion so decides, be consolidated for

trial by order (issued after giving all parties reasonable notice and opportunity to be heard) of such court and tried in—

(1) any district which is selected by such defendant and in which one of such actions is pending,

(2) a district which is agreed upon by stipulation between all the parties to such actions and in which one of such actions is pending, or

(3) a district which is selected by the court and in which one of such actions is pending.

15 U.S.C. § 2620

§2620. Citizens' petitions

(a) In general

Any person may petition the Administrator to initiate a proceeding for the issuance, amendment, or repeal of a rule under section 2603, 2605, or 2607 of this title or an order under section 2603 or 2604(e) or (f) of this title.

(b) Procedures

(1) Such petition shall be filed in the principal office of the Administrator and shall set forth the facts which it is claimed establish that it is necessary to issue, amend, or repeal a rule under section 2603, 2605, or 2607 of this title or an order under section 2603 or 2604(e) or (f) of this title.

(2) The Administrator may hold a public hearing or may conduct such investigation or proceeding as the Administrator deems appropriate in order to determine whether or not such petition should be granted.

(3) Within 90 days after filing of a petition described in paragraph (1), the Administrator shall either grant or deny the petition. If the Administrator grants such petition, the Administrator shall promptly commence an appropriate proceeding in accordance with section 2603, 2604, 2605, or 2607 of this title. If the Administrator denies such petition, the Administrator shall publish in the Federal Register the Administrator's reasons for such denial.

(4)(A) If the Administrator denies a petition filed under this section (or if the Administrator fails to grant or deny such petition within the 90-day period) the petitioner may commence a civil action in a district court of the United States to compel the Administrator to initiate a rulemaking proceeding as requested in the petition. Any such action shall be filed within 60 days after the Administrator's denial of the petition or, if the Administrator fails to grant or deny the petition within 90 days after filing the petition, within 60 days after the expiration of the 90-day period.

(B) In an action under subparagraph (A) respecting a petition to initiate a proceeding to issue a rule under section 2603, 2605, or 2607 of this title or an order under section 2603 or 2604(e) or (f) of this title, the petitioner shall be provided an opportunity to have such petition considered by the court in a de novo proceeding. If the petitioner demonstrates to the satisfaction of the court by a preponderance of the evidence that—

(i) in the case of a petition to initiate a proceeding for the issuance of a rule under section 2603 of this title or an order under section 2603 or 2604(e) of this title—

(I) information available to the Administrator is insufficient to permit a reasoned evaluation of the health and environmental effects of the chemical substance to be subject to such rule or order; and

(II) in the absence of such information, the substance may present an unreasonable risk to health or the environment, or the substance is or will be produced in substantial quantities and it enters or may reasonably be anticipated to enter the environment in

substantial quantities or there is or may be significant or substantial human exposure to it; or

(ii) in the case of a petition to initiate a proceeding for the issuance of a rule under section 2605(a) or 2607 of this title or an order under section 2604(f) of this title, the chemical substance or mixture to be subject to such rule or order presents an unreasonable risk of injury to health or the environment, without consideration of costs or other nonrisk factors, including an unreasonable risk to a potentially exposed or susceptible subpopulation, under the conditions of use.[1]

the court shall order the Administrator to initiate the action requested by the petitioner. If the court finds that the extent of the risk to health or the environment alleged by the petitioner is less than the extent OF risks to health or the environment with respect to which the Administrator is taking action under this chapter and there are insufficient resources available to the Administrator to take the action requested by the petitioner, the court may permit the Administrator to defer initiating the action requested by the petitioner until such time as the court prescribes.

(C) The court in issuing any final order in any action brought pursuant to subparagraph (A) may award costs of suit and reasonable fees for attorneys and expert witnesses if the court determines that such an award is appropriate. Any court, in issuing its decision in an action brought to review such an order, may award costs of suit and reasonable fees for attorneys if the court determines that such an award is appropriate.

(5) The remedies under this section shall be in addition to, and not in lieu of, other remedies provided by law

RELEVANT PROVISIONS OF THE ADMINISTRATIVE PROCEDURE ACT

5 U.S.C. § 553 – Rulemaking

(a) This section applies, according to the provisions thereof, except to the extent that there is involved-

(1) a military or foreign affairs function of the United States; or

(2) a matter relating to agency management or personnel or to public property, loans, grants, benefits, or contracts.

(b) General notice of proposed rulemaking shall be published in the Federal Register, unless persons subject thereto are named and either personally served or otherwise have actual notice thereof in accordance with law. The notice shall include-

(1) a statement of the time, place, and nature of public rule making proceedings;

(2) reference to the legal authority under which the rule is proposed;

(3) either the terms or substance of the proposed rule or a description of the subjects and issues involved; and

(4) the Internet address of a summary of not more than 100 words in length of the proposed rule, in plain language, that shall be posted on the Internet website under

section 206(d) of the E-Government Act of 2002 (44 U.S.C. 3501 note) (commonly known as regulations.gov).

Except when notice or hearing is required by statute, this subsection does not apply-

(A) to interpretative rules, general statements of policy, or rules of agency organization, procedure, or practice; or

(B) when the agency for good cause finds (and incorporates the finding and a brief statement of reasons therefor in the rules issued) that notice and public procedure thereon are impracticable, unnecessary, or contrary to the public interest.

(c) After notice required by this section, the agency shall give interested persons an opportunity to participate in the rule making through submission of written data, views, or arguments with or without opportunity for oral presentation. After consideration of the relevant matter presented, the agency shall incorporate in the rules adopted a concise general statement of their basis and purpose. When rules are required by statute to be made on the record after opportunity for an agency hearing, sections 556 and 557 of this title apply instead of this subsection.

(d) The required publication or service of a substantive rule shall be made not less than 30 days before its effective date, except-

(1) a substantive rule which grants or recognizes an exemption or relieves a restriction;

(2) interpretative rules and statements of policy; or

(3) as otherwise provided by the agency for good cause found and published with the rule.

(e) Each agency shall give an interested person the right to petition for the issuance, amendment, or repeal of a rule.